

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA

ex rel. [UNDER SEAL],

and on behalf of the STATES of CALIFORNIA,
COLORADO, CONNECTICUT, DELAWARE,
THE DISTRICT OF COLUMBIA, FLORIDA,
GEORGIA, HAWAII, ILLINOIS, INDIANA,
IOWA, LOUISIANA, MARYLAND,
MASSACHUSETTS, MICHIGAN,
MINNESOTA, MONTANA, NEVADA, NEW
JERSEY, NEW MEXICO, NEW YORK, NORTH
CAROLINA, OKLAHOMA, RHODE ISLAND,
TENNESSEE, TEXAS, VERMONT, VIRGINIA,
and WASHINGTON,

ex rel. [UNDER SEAL],

Plaintiffs,

vs.

[UNDER SEAL],

Defendants.

Case No. 2:22-cv-04479-GJP

JURY TRIAL DEMANDED

**QUI TAM AMENDED COMPLAINT
FOR VIOLATIONS OF THE FEDERAL
FALSE CLAIMS ACT, 31 U.S.C. §§ 3729,
et seq., AND ANALOGOUS STATE FALSE
CLAIMS ACTS,
AND VIOLATIONS OF THE CALIFORNIA
INSURANCE FRAUD PREVENTION ACT,
CAL. INS. CODE § 1871.7 *et seq.*,
AND VIOLATIONS OF THE INSURANCE
CLAIMS FRAUD PREVENTION ACT, 740
ILL. COMP. STAT. 92/1 *et seq.***

**UNDER SEAL
Pursuant to 31 U.S.C. § 3730(b)(2)**

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA, *ex rel.*
ZILMA H. COLÓN, and on behalf of the
STATES of CALIFORNIA, COLORADO,
CONNECTICUT, DELAWARE, THE
DISTRICT OF COLUMBIA, FLORIDA,
GEORGIA, HAWAII, ILLINOIS, INDIANA,
IOWA, LOUISIANA, MARYLAND,
MASSACHUSETTS, MICHIGAN,
MINNESOTA, MONTANA, NEVADA, NEW
JERSEY, NEW MEXICO, NEW YORK,
NORTH CAROLINA, OKLAHOMA, RHODE
ISLAND, TENNESSEE, TEXAS, VERMONT,
VIRGINIA, and WASHINGTON, *ex rel.*
ZILMA H. COLÓN,

Plaintiff-Relator,

vs.

ZOLL MEDICAL CORPORATION and ASAHI
KASEI CORPORATION,

Defendants.

Case No. 2:22-cv-04479-GJP

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FOR VIOLATIONS OF THE
FEDERAL FALSE CLAIMS ACT, 31
U.S.C. §§ 3729, *et seq.*, AND
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CALIFORNIA INSURANCE FRAUD
PREVENTION ACT, CAL. INS.
CODE § 1871.7 *et seq.*,
AND VIOLATIONS OF THE
INSURANCE CLAIMS FRAUD
PREVENTION ACT, 740 ILL.
COMP. STAT. 92/1 *et seq.***

**UNDER SEAL
Pursuant to 31 U.S.C. § 3730(b)**

JURY TRIAL DEMANDED

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I. NATURE OF THE CASE

1. *Qui tam* Relator Zilma H. Colón (“Relator”) brings this action under the False Claims Act, 31 U.S.C. § 3729, *et seq.* (the “FCA”) on behalf of the United States of America. Relator also brings this action, under the relevant analogous state false claims statutes (herein, the “State FCAs”), on behalf of the individual states, of California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington (the “Plaintiff States”). Hereinafter, the United States of America and the Plaintiff States will be referred to, collectively, as the “Government.”

2. Relator brings this action against Defendants Zoll Medical Corporation (“Zoll” or the “Company”) and Asahi Kasei Corporation (together, “Defendants”) to recover funds Defendants have defrauded from the Government funded healthcare programs known as Medicare, Medicaid, TRICARE, the Department of Veterans Affairs (the “VA”), the Federal Employee Health Benefits Program (“FEHB”), and any other federally funded health benefits program (together, the “Government Funded Healthcare Programs” or simply the “Government”).

3. This case seeks to recover damages and civil penalties arising from false claims for payment that Defendant Zoll, a medical device manufacturer, submitted for reimbursement to the Government Funded Healthcare Programs for monthly rentals of its wearable cardioverter defibrillator, a medical device that Zoll manufactures and distributes under the brand name LifeVest. The claims are false for the reasons alleged in detail throughout the rest of the Complaint.

4. To summarize, for at least the last six years, Defendants have submitted many thousands of claims for reimbursement to the Government Funded Healthcare Programs (and received many millions of dollars from the Government in return) for ongoing monthly rentals of Zoll’s LifeVest that were not “reasonable and necessary” due to patient non-usage.¹ *See* 42 U.S.C.

¹ Zoll rents its LifeVest to patients on a monthly basis usually for periods of three or more months at a time. Throughout the Complaint, Relator uses the phrase “ongoing monthly rental” to refer to the months that follow a patient’s first month of renting a device. For example, if a device is rented for three months, the Complaint refers to the second and third months as the ongoing monthly

§§ 1395y(a)(1)(A) and (B). Suppliers of medical devices such as Zoll must ensure that the equipment they rent to beneficiaries of the Government Funded Healthcare Programs is “reasonable and necessary” *throughout the entire rental period*. For ongoing rental periods, the Government places a responsibility on the supplier – not the patients’ physicians – to verify that program beneficiaries *continue to use* their equipment and have a *continued need* for it before billing for the ongoing rental period.

5. In the present case, Zoll knows that patients must use (in this case wear) their LifeVests in order to receive the reasonable and necessary medical benefit that a LifeVest can provide. Despite this knowledge, Zoll continues to bill the Government Funded Healthcare Programs for ongoing monthly rentals of its LifeVests ***even when Zoll’s own records prove that the patients have completely stopped using their LifeVests***. Zoll’s patients are literally not using their LifeVests – at all – for consecutive days, weeks and even months at a time but Zoll continues to bill the Government for the rentals anyway.

6. Moreover, Zoll’s false billing for unworn LifeVests is not an isolated occurrence. Zoll routinely and systematically bills the Government Funded Healthcare Programs for LifeVests that are no longer being used by the beneficiaries. Zoll has a system for monitoring patient usage for all of its LifeVests. Based on this system, Zoll’s own records show, and Zoll is well aware, that only a small percentage of patients actually wear their LifeVests continuously as directed by Zoll and by the patients’ physicians. Rather, Zoll’s own records show that for at least 50% of the months that Zoll bills the Government for a rental of its device, the patients have never worn the Life Vest *at all*, for the entire month that Zoll has sought and received reimbursement – a massive problem with patient non-usage. Despite the huge problem Zoll has with patients not using their LifeVests, Zoll bills the Government anyway, for the whole length of virtually every patient’s full

rental periods. This distinction between the first month and the subsequent months is crucial to Relator’s allegations. That is because, after the initial month, the Government Funded Healthcare Programs require, *as a condition of payment*, that the provider verify that the patient *continues to use* the product and has a *continued need* for the product before the Government will pay for an ongoing monthly rental period.

prescription, and even for reorders of additional months of the LifeVest, even though the patients have never even used the LifeVest at all during the ongoing monthly rental periods.

7. When it is being worn, the LifeVest saves lives. That is because the device is intended to be worn by patients who are at high risk for sudden cardiac arrest (“SCA”), an often-deadly event. The LifeVest has a built-in defibrillator that “shocks” a person back to life if the person develops a sudden cardiac arrest *while wearing the LifeVest*. The problem is that the LifeVest is bulky, uncomfortable, and plagued by numerous anxiety-inducing false alarms. As a result, many patients simply stop wearing their LifeVests and never put them on again. Zoll knows this but keeps billing even when the LifeVests are no longer being used.

8. Worse than that, Zoll’s false billing scheme also leads to substantial patient harm. In order to keep billing for patients who are not using their LifeVests, Zoll has a policy of not reaching out to non-compliant patients to encourage them to use their LifeVest and not reaching out to the patients’ doctors to tell them about their patients’ non-usage. Zoll has this policy because, first, if it reached out to the patients, many of them would simply return their LifeVests to Zoll depriving Zoll of additional revenue. This causes patient harm because the patients continue to be at high-risk for SCA but they are not being encouraged to wear their lifesaving LifeVests. So, while Zoll stays silent continuing to bill for the LifeVests, the patients remain at high risk for SCA.

9. Second, Zoll does not reach out to tell the doctors about their patients’ non-usage because the doctors would likely intervene. Specifically, doctors have a number of medical steps they can take to assist high-risk patients who are not wearing their LifeVests – steps that would help save the patient’s life but would eliminate a need for the LifeVest, depriving Zoll of additional revenue. The patient harm here is obvious: by not telling the doctors about their patients’ non-usage, Zoll gets to continue falsely billing for the LifeVest but it deprives the patients of the doctor’s medical assistance and leaves the patients at high-risk for SCA.

10. For all of the reasons set forth here and throughout the Complaint, each one of the claims submitted by Zoll for patients who are not using their LifeVests is knowingly false, in violation of the FCA, because Zoll knew the ongoing rentals were not being used by the patients

and thus they did not meet the Government's requirement that the rental item be reasonable and necessary.

11. Defendants' fraudulent scheme was carried out nationwide across all states, territories and jurisdictions. As a result, Defendants' conduct not only violated the federal FCA, but it also violated analogous state false claims acts and healthcare fraud remedial statutes of the Plaintiff States and the District of Columbia (the "State Statutes"). Like the federal False Claims Act, the State Statutes impose liability for defined conduct in the nature of fraud, for the submission of false claims, the use of false records and documents, and the failure to disclose material information, in presenting claims to each respective sovereign's Medicaid program. As described throughout the Complaint and as alleged in Counts 3–35 found at the end of this Complaint, the conduct of the Defendants not only violated the federal FCA, but it also violated the State Statutes of the Plaintiff States.

II. JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction pursuant to 31 U.S.C. §§ 3732(a) and (b), which specifically confer jurisdiction on this Court to hear actions brought under 31 U.S.C §§ 3729 and 3730 of the FCA. This Court also has jurisdiction pursuant to 28 U.S.C. § 1331.

13. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because one or more Defendants can be found, reside, and/or transact business in this District and/or because acts proscribed by 31 U.S.C. § 3729 occurred within this District. This Court also has personal jurisdiction over Defendants because Defendants have systematically, continuously, and purposefully availed themselves of the privilege of doing business in this District, and because many of Defendants' acts giving rise to the violations alleged herein occurred in this District.

14. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), and 31 U.S.C. § 3732(a), because many of the events or omissions giving rise to the violations of 31 U.S.C. § 3729, as alleged in the Complaint, occurred in this District.

15. This action is not based upon the prior public disclosure of allegations or transactions in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party, in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation, in the news media, or in any other form as the term “publicly disclosed” is defined in 31 U.S.C. § 3730(e)(4)(A).

16. To the extent there has been a public disclosure unknown to Relator, she is an original source under 31 U.S.C. § 3730(e)(4)(B).

III. PARTIES

17. Relator Zilma H. Colón is a former Senior Territory Manager for Zoll. Relator worked for Zoll for almost five years from July 3, 2017 to June 18, 2022. During her first two years at Zoll, Relator worked as a Territory Manager (“TM”) and for the last three years, she held the position of Senior Territory Manager. Throughout her time at Zoll, Relator’s primary responsibility was to sell Zoll’s wearable cardioverter defibrillator (“WCD”) to healthcare providers in her geographic territory, an area which encompassed most of the southwest portion of the United States territory of Puerto Rico. While at Zoll, Relator reported to managers who oversee a larger region which includes all of Puerto Rico and most of the State of Florida. Relator regularly attended sales meetings either in person or by videoconference for her larger region and also annual meetings for the entire U.S. sales force at Zoll.

18. Defendant Zoll develops and markets medical devices and related computer software focused on the field of emergency medical care. Zoll manufactures and sells products world-wide for defibrillation and cardiac monitoring, circulation enhancement and CPR feedback, supersaturated oxygen therapy, data management, ventilation, therapeutic temperature management, and sleep apnea diagnosis and treatment. Zoll is the leading and best-selling manufacturer of WCDs in the United States. Zoll distributes its WCD device throughout the United States and the world under the brand name LifeVest. *See* Complaint at paras. 97–103 for a description of WCDs in general and paras. 104–114 for a description of the Zoll LifeVest in particular.

19. Defendant Asahi Kasei Corporation is a large corporate conglomerate headquartered in Tokyo, Japan with annual revenue of approximately \$20 billion. Asahi Kasei operates internationally and is Japan's leading diversified chemical manufacturer with businesses in the healthcare, chemicals, construction materials, and electronics sectors. In April 2012, Asahi Kasei acquired Zoll through a purchase of all of Zoll's outstanding shares.

20. The United States of America and the Plaintiff States are parties-in-interest in this matter because it is the Government who actually paid the false claims alleged in this Complaint. Under the FCA and the State FCAs, the United States of America and the Plaintiff States are entitled to most of the monetary recovery sought by this action.

21. The Federal Government paid false claims, *inter alia*, as part of its operation and implementation of the Medicare program, a federal health insurance program administered by the Centers for Medicare and Medicaid Services ("CMS") on behalf of the elderly and disabled. 42 U.S.C. §§ 1395-1395hhh. The Federal Government and the Plaintiff States, together, also paid false claims as part of their operation and implementation of the Medicaid program, a jointly funded federal and state public assistance program, also administered by CMS, which pays for medical services for qualified low-income people. 42 U.S.C. §§ 1396-1396v. The Federal Government also paid false claims as part of its operation and implementation of TRICARE, the healthcare program for the country's active duty, uniformed military service members and their families. 10 U.S.C. § 1071 *et seq.* And, the Federal Government also paid false claims as part of its operation and implementation of the healthcare benefits the Federal Government provides to veterans through the VA. 38 U.S.C. § 101 *et seq.* and the FEHB program, established under Chapter 89 of Title 5 of the U.S. Code, 5 U.S.C. §§ 8901 through 8914.

22. Together, Medicare, Medicaid, TRICARE, the VA, and the FEHB programs constitute the Government Funded Healthcare Programs that paid the false claims at issue in this case.

IV. STATUTES, RULES AND REGULATIONS

A. The Federal False Claims Act and Analogous State False Claims Acts

23. The FCA imposes liability on any person who knowingly presents, or causes to be presented, a false or fraudulent claim to the Federal Government for payment of money (a “false claim”). 31 U.S.C. § 3729(a)(1)(A). The FCA defines “claim” to include any request or demand, whether under contract or otherwise, for money that is made to an agent of the United States or to a contractor if the money is to be spent to advance a government program or interest and the government provides or will reimburse any portion of the money. 31 U.S.C. § 3729(b)(2). Requests for reimbursement submitted to the Government Funded Healthcare Programs, as defined in this case, are all considered “claims” for purposes of the FCA.

24. The FCA defines “knowingly” to mean actual knowledge, deliberate ignorance of truth or falsity, or reckless disregard of truth or falsity. Specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1).

25. The FCA also imposes liability on any person who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim (a “false statement”). 31 U.S.C. § 3729(a)(1)(B). The FCA defines “material” to mean having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property. 31 U.S.C. § 3729(b)(4).

26. In addition, the FCA provides for the award of treble damages and civil penalties for knowingly submitting, or causing the submission of, false or fraudulent claims for payment to the Government or for making or using false statements material to false or fraudulent claims paid for by the Government. 31 U.S.C. § 3729(a)(1)(2).

27. The Plaintiff States have enacted their own false claims statutes, which parallel the federal statute and provide comparable relief to the respective state for the submission of false and fraudulent claims. *See* California False Claims Act, Cal. Gov’t Code § 12650, *et seq.*; Colorado Medicaid False Claims Act, Col. Rev. Stat. §§ 25.5-4-303.5 to 25.5-4-310; Connecticut False Claims Act, Conn. Gen. Stat. § 4-274 *et seq.*; Delaware False Claims & Reporting Act, 6 Del.

Code § 1201 *et seq.*; District of Columbia False Claims Act, D.C. Code § 2-381.01 *et seq.*; Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*; Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*; Hawaii False Claims Law, HRS § 661-21 *et seq.*; Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq.*; Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5-1 *et seq.*; Iowa False Claims Act, Iowa Code § 685.1 *et seq.*; Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:438.1 *et seq.*; Maryland False Health Claims Act, Md. Code Ann. Health-Gen. § 2-601 *et seq.*; Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12 § 5A *et seq.*; Michigan Medicaid False Claims Act, Mich. Comp. Laws Ann. § 400.601, *et seq.*; Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*; Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*; Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. § 357.010 *et seq.*; New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*; New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1 *et seq.*; New York False Claims Act, N.Y. State Fin. Law, Art. 13, § 187 *et seq.*; North Carolina False Claims Act, N.C. Gen. Stat. Ann. § 1-605 *et seq.*; Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. tit. 63, § 5053.1 *et seq.*; Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*; Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*; Texas False Claims Act, Texas Human Resources Code, § 36.001 *et seq.*; Vermont False Claims Act, Vt. Stat. Ann. tit. 32 § 630 *et seq.*; Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*; and, Washington State Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66, *et seq.* (collectively, the “State FCAs”).

B. The California Insurance Fraud Prevention Act

28. CIFPA, Cal. Ins. Code § 1871.7 *et seq.*, prohibits insurance fraud and is designed “to facilitate the investigation and prosecution of insurance fraud.” *People ex rel. Allstate Ins. Co. v. Weitzman*, 107 Cal. App. 4th 534, 548, 132 Cal. Rptr. 2d 165, 175 (Cal. Ct. App. 2003), *as modified on denial of reh’g* (Cal. Ct. App. Apr. 24, 2003).

29. The California Legislature enacted CIFPA to combat abusive practices aimed at defrauding private insurance providers. The legislative findings and declarations associated with Section 1871.7 make clear that the Legislature was specifically concerned with fraud on health insurance providers: “Health insurance fraud is a particular problem for health insurance policyholders. Although there are no precise figures, it is believed that fraudulent activities account for billions of dollars annually in added health care costs nationally. Health care fraud causes losses in premium dollars and increases health care costs unnecessarily.” Cal. Ins. Code § 1871(h).

30. With respect to insurance fraud subject to the CIFPA, “[i]nsurers, not the state government, are the direct victims of the fraud” and “[i]nsureds are the indirect victims who pay higher premiums due to the prevalence of insurance fraud.” *Weitzman*, 107 Cal. App at 452. As a result, “[t]he general public also benefits from qui tam actions to enforce Insurance Code section 1871.7, because fraudulent insurance claims result in higher premiums.” *People ex rel. Strathmann v. Acacia Research Corp.*, 210 Cal. App. 4th 487, 504, 148 Cal. Rptr. 3d 361, 373 (Cal. Ct. App. 2012).

31. Under CIFPA, “[e]very person who violates any provision of this section or Section 549, 550, or 551 of the Penal Code shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than five thousand dollars (\$5,000) nor more than ten thousand dollars (\$10,000), plus an assessment of not more than three times the amount of each claim for compensation.” Cal. Ins. Code § 1871.7(b). The Court may also order equitable and injunctive relief. *Id.*

32. Under CIFPA, “[t] it is unlawful to knowingly employ runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits . . . or to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer.” Cal. Ins. Code § 1871.7(a).

33. In addition, CIFPA incorporates Section 549, 550, or 551 of the California Penal Code and violations of Section 549, 550, or 551 of the California Penal Code are actionable under CIFPA. Cal. Ins. Code § 1871.7(b).

34. Section 550 of the California Penal Code prohibits, *inter alia*, “[k]nowingly present[ing] or caus[ing] to be presented any false or fraudulent claim for the payment of a loss or injury, including payment of a loss or injury under a contract of insurance” and “[k]nowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit.” Cal. Penal Code §§ 550(a)(1), (6).

35. To establish a violation of Cal. Penal Code § 550, a plaintiff need only prove (1) presentment or causing the presentment of a false claim and (2) the intent to defraud. *People ex rel. Gov’t Employees Ins. Co. v. Cruz*, 244 Cal. App. 4th 1184, 1193–94, 198 Cal. Rptr. 3d 566, 574 (Cal. Ct. App. 2016). Thus, “[i]t is not necessary that anyone actually be defrauded or actually suffer a financial, legal, or property loss as a result of the defendant’s acts.” *Id.* at 1194 (internal quotation marks omitted).

36. CIFPA authorizes “any interested person” to bring a claim for a violation of the CIFPA in the name of the state. Cal. Ins. Code § 1871.7(e)(1). In this way, CIFPA “enable[s] and encourage[s] the enforcement of regulatory provisions, such as section 1871.7, that would otherwise be beyond the resources of public entities to enforce.” *State ex rel. Wilson v. Superior Court*, 227 Cal. App. 4th 579, 596, 174 Cal. Rptr. 3d 317, 328 (Cal. Ct. App. 2014), *as modified on denial of reh’g* (July 25, 2014).

C. The Illinois Insurance Claims Fraud Prevention Act

37. IICFPA, 740 Ill. Comp. Stat. 92/1 *et seq.*, provides that “it is unlawful to knowingly offer or pay any remuneration directly or indirectly, in cash or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance.” 740 Ill. Comp. Stat. 92/5(a).

38. IICFPA further provides that “[a] person who violates any provision of this Act, Section 17-8.5 or Section 17-10.5 of the Criminal Code of 1961 or the Criminal Code of 2012, or

Article 46 of the Criminal Code of 1961 shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than \$5,000 nor more than \$10,000, plus an assessment of not more than 3 times the amount of each claim for compensation under a contract of insurance.” 740 Ill. Comp. Stat. 92/5(b).

39. IICFPA authorizes “an interested person” to bring a claim for a violation of IICFPA on behalf of the State of Illinois. 740 Ill. Comp. Stat. 92/15(a).

D. The Government Funded Healthcare Programs

1. Medicare

40. Medicare is a federal health insurance program created by Congress in 1965 for the elderly and certain categories of disabled persons. It is the nation’s largest health insurance program, covering more than 45 million people. Medicare is administered by CMS.

41. Medicare directly pays doctors, hospitals, pharmacies, laboratories, and many other types of healthcare providers, including manufacturers and suppliers of medical devices such as Defendants, for their goods and services. Payments are set according to conditions and rates established by the Government.

42. Medicare is divided into four parts: Medicare Parts A, B, C, and D, two of which – Parts B and C – are relevant to this case. Medicare Part B, often referred to as traditional Medicare, authorizes the payment of federal funds directly to providers for *reasonable and necessary* outpatient health services and associated products. Medicare Part B will pay for *reasonable and necessary* durable medical equipment (“DME”), including the product that is the subject matter of this case: the Zoll LifeVest. *See* 42 U.S.C. §§ 1395y(a)(1)(A) and (B). *See* Complaint at paras. 58–73 for a description of Medicare’s overall participation and reimbursement requirements. *See also* Complaint at paras. 115–138 for a description of Medicare’s specific coverage and conditions of payment for the Zoll Life Vest.

43. Medicare defines DME as products which meet all of the following criteria:

- Durable (can withstand repeated use)
- Used for a medical reason

- Not usually useful to someone who is not sick or injured
- Used in the home

44. The Zoll WCD at issue in this case, the LifeVest, qualifies as DME under Medicare’s definition. *See* Complaint at paras. 104–114 for a detailed description of the Zoll LifeVest.

45. Medicare Part B pays for different kinds of DME in different ways. Depending on the type of equipment, Medicare Part B may pay a monthly fee to rent the equipment for the patient (a monthly rental); Medicare may buy the equipment for the patient; or Medicare may pay a monthly fee that, after a pre-set number of monthly payments, turns a rental into a purchase of the equipment for the benefit of the patient (a capped rental). *Medicare Part B pays for the DME item at issue in this case, the Zoll LifeVest, on a monthly rental basis when it is reasonable and necessary.* *See* Complaint at paras. 58–73 and 115–138 for a full description of the applicability of Medicare’s regulations, coverage requirements, and conditions of payment for Zoll’s LifeVest.

46. Under Medicare Part C (known as the “Medicare Advantage Program”), 42 C.F.R. Part 422, CMS authorizes private insurers to offer health insurance plans to individuals who are eligible for Medicare. The private insurance plans offered through the Medicare Advantage Program are called Medicare Advantage Plans and they are paid for in full by federal government funds. *Under Part C, the Medicare Advantage Plans also pay for Zoll’s LifeVest on a monthly rental basis.*

47. The private insurers offering Medicare Advantage Plans are all managed care organizations (“MCOs”) who contract with CMS to administer Part C benefits. They are required to provide the same level of service as available through traditional Medicare Part B. Importantly, all of the protections, regulations, coverage requirements, and conditions of payment applicable to Medicare Part B, *see* Complaint at paras. 58–73 and 115–138, equally apply to the work of the MCOs under Medicare Part C, including the requirement that Medicare only pays for Zoll’s LifeVests that are *reasonable and necessary*. Pursuant to their contracts with CMS, the MCOs are

paid a capitated rate based, *inter alia*, on the number of Medicare beneficiaries they service and the level of illness of those beneficiaries.

48. Medical services undergone by the beneficiaries who participate in the MCOs' Medicare Advantage plans are billed to the MCOs for payment. All such insurance claims paid by MCOs, as well as the MCOs' associated administrative costs, are paid using funds provided by the Federal Government through CMS's capitated payments.

2. Medicaid

49. The Medicaid program was created in 1965 as part of the Social Security Act. It authorizes federal grants to states for medical assistance to qualifying low-income persons. The Medicaid program is jointly financed by federal and state governments. CMS administers Medicaid on the federal level. Within broad federal rules, each state decides its program's eligible groups, types, range of services, payment levels, and administrative and operating procedures.

50. Under Medicaid, the states directly pay doctors, hospitals, pharmacies, laboratories, and many other types of healthcare providers, including DME manufacturers and suppliers of medical devices, such as Defendants, for their goods and services. Payments are set according to conditions and rates established by each particular state's Medicaid program. The states obtain the federal share of the payments made by the states to the healthcare providers from accounts which draw on the United States Treasury. *See* 42 U.S.C. §§ 396, *et seq.*, and 42 C.F.R. §§ 430.0-430.30. The federal share of each state's Medicaid expenditures varies by state.

51. In all relevant aspects, Medicaid's participation and reimbursement requirements for providers match those for participation and reimbursement under Medicare, including the requirement that Medicaid, like Medicare, will only pay for DME items that are *reasonable and necessary*. *See* Complaint at paras. 58–73 (description of Medicare's participation and reimbursement requirements). As with Medicare, the Plaintiff States' Medicaid programs will cover Zoll's LifeVest, on a monthly rental basis, when it is reasonable and necessary. *See* Complaint at paras. 115–138 (description of Medicare's comparable coverage and conditions of payment for the Zoll Life Vest).

3. TRICARE

52. TRICARE is a federal healthcare program which provides civilian health benefits for active military personnel, military retirees, and their families worldwide. TRICARE, formerly known as CHAMPUS, is administered by the Defense Health Agency under the Department of Defense and funded by the Federal Government. TRICARE offers a triple option benefit plan: an HMO option; a PPO option; and a fee for service option. *See* 10 U.S.C. §§ 1071-1110.

53. At all relevant times, applicable TRICARE regulations relating to coverage of claims by providers and physicians have been substantially similar to the applicable Medicare provisions described herein. The regulatory authority establishing the TRICARE program provides reimbursement to individual health care providers applying, to the extent practicable, the same reimbursement scheme and coding parameters that the Medicare program applies. 10 U.S.C. § 1079(h)(1) (individual health care professional) (citing 42 U.S.C. § 1395, *et seq.*).

54. TRICARE's participation and reimbursement requirements and practices closely align with the specific rules and regulations for participation and reimbursement under Medicare. *See* Complaint at paras. 58–73 (description of Medicare's participation and reimbursement requirements). As with Medicare, TRICARE will cover Zoll's LifeVest, on a monthly rental basis, when it is reasonable and necessary. *See* Complaint at paras. 115–138 (description of Medicare's comparable conditions of payment for the Zoll Life Vest).

4. The Department of Veterans Affairs

55. During the relevant time period, Zoll has also rented numerous LifeVests to veterans covered by the healthcare programs administered by the VA. At all relevant times, the applicable VA healthcare regulations relating to coverage of claims by providers have been substantially similar in all material respects, including the requirement that rental of the LifeVest must be reasonable and necessary, to the applicable Medicare provisions described herein. *See* Complaint at paras. 58–73 and 115–138.

5. The Federal Employees Health Benefits Program

56. The Government, through the U.S. Office of Personnel Management (“OPM”), funds and oversees the FEHB program. The FEHB program provides healthcare benefits, including coverage of DME rental items such as the LifeVest, for certain Federal government employees and retirees, including their family members and survivors. *See* 5 U.S.C. § 8901 et seq.

57. In all relevant aspects, the FEHB program’s participation and reimbursement requirements for providers are similar to those for participation and reimbursement under Medicare, including the requirement that the FEHB program, like Medicare, will only pay for DME items that are reasonable and necessary. *See* Complaint at paras. 58–73 and 115–138.

E. Rules and Requirements for Provider Participation and Reimbursement under Medicare and the Other Government Funded Healthcare Programs

58. *Zoll participates* in the Government Funded Healthcare Programs and also *directly seeks reimbursement* from the Government Funded Healthcare Programs for the rental of its LifeVests. Zoll does so because it is the manufacturer and it is also the DME supplier of the LifeVests that Zoll rents on a monthly basis to beneficiaries of the Government Funded Healthcare Programs. There is no middleman between Zoll and the Government. Thus, Zoll directly rents its LifeVests to beneficiaries of the Government Funded Healthcare Programs; Zoll directly seeks reimbursement from the Government Funded Healthcare Programs for the monthly rentals of its LifeVests; Zoll signs the claim forms and certifications that it submits to the Government Funded Healthcare Programs seeking reimbursement for its LifeVest rentals, and Zoll is the one who the Government pays for the rental of its LifeVests by the beneficiaries of the Government Funded Healthcare Programs.

59. This section of the Complaint describes the rules and requirements that Zoll must meet in order to participate in, and seek reimbursement from, the Government Funded Healthcare Programs. This section starts off with a full description of the participation and reimbursement requirements for the Medicare program (the largest program) and then goes on to provide an overview of the applicability of the Medicare requirements to certain Government Funded

Healthcare Programs at issue in this case, including Medicaid, TRICARE, the VA, and the FEHB program.

60. Medicare's most important governing principle is the following: Medicare will only pay for healthcare services or products that are "reasonable and necessary." 42 U.S.C. §§ 1395y(a)(1)(A) and (B). No other statutory requirement is more important to Medicare for the safe and cost-effective administration of its program. In furtherance of this principle, when the Government pays for a DME item on an ongoing rental basis, as is the case with Zoll's LifeVest, *Medicare considers a patient's failure to use a rented device as conclusive evidence the product was not reasonable and necessary for that particular patient.* See Complaint at paras. 118–121 and 135–137. Zoll's conduct, as alleged in this Complaint, violates this bedrock principle.

61. That a service or product must be reasonable and necessary is so important to the Medicare program that healthcare providers who wish to participate in the program must certify – in order to enroll in the program – that they have met and that they will continue to meet this requirement. Once enrolled in Medicare, all healthcare providers must also certify on each and every request for reimbursement that they submit to Medicare that the service or product is reasonable and necessary. Without making such a certification – on each and every request for reimbursement – Medicare will not pay the provider for the submitted claim.

1. Participation Requirements for Medicare and the Other Government Funded Healthcare Programs

62. All healthcare providers who wish to participate in Medicare must first enroll in the program. Form CMS-855B is the appropriate Medicare Enrollment Application form that all healthcare providers, including Zoll, must use to enroll in Medicare. The form is used to establish a healthcare provider's eligibility to participate in the Medicare program. Once eligibility is established and the provider is enrolled in Medicare, every five years each provider must revalidate its enrollment by completing and submitting another Form CMS-855.

63. Form CMS-855 contains a Certification Statement which the healthcare provider must sign when it enrolls in Medicare and again each time the provider seeks to revalidate its

enrollment. This certification, among other things, states that signing the document “legally and financially binds the [healthcare provider] to the laws, regulations, and program instructions of the Medicare program.” By signing the statement, the healthcare provider also certifies that it has read the information provided in the enrollment form and that the information is “true, correct, and complete” and that the provider takes on a duty to correct any information subsequently found not to be true, correct or complete.

64. The Certification Statement found in Section 15 of Form CMS-855B also contains the following language which is directly on point with respect to the allegations of the Complaint:

1. I agree to abide by the Medicare laws, regulations and program instructions that apply . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions and

2. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

65. Defendant Zoll has been enrolled in Medicare as a healthcare provider for many years. In its initial enrollment document, and in every revalidation since, Zoll has signed the Certification Statement found in Section 15 of Form CMS-855B and submitted it to Medicare. These certifications show that Defendant Zoll understands it is legally and financially required to comply with all Medicare laws, rules, regulations, and program instructions, *including the statutory requirement that any request for reimbursement from Medicare must be for services or products that are “reasonable and necessary.”* See 42 U.S.C. §§ 1395y(a)(1)(A) and (B). The Section 15 certifications also show that Defendant Zoll agreed to abide by these same Medicare requirements.

66. As alleged throughout this Complaint, the certifications that Defendant Zoll has made on its Form CMS-855B submissions were false when submitted because Defendants have submitted many thousands of claims for reimbursement, for the ongoing rental of its LifeVests,

that were not reasonable and necessary in violation of Medicare’s “laws, regulations, and program instructions.”

2. Reimbursement Requirements for Medicare and the Other Government Funded Healthcare Programs

67. Once enrolled in Medicare, all healthcare providers must submit a Medicare Health Insurance Claim Form, known as a CMS-1500 claim form or its electronic equivalent (“CMS-1500”),² for each specific product or service for which it seeks reimbursement. This form requires certain specific information that must be provided in order to receive payment. Among other things, it requests the NPI number of the healthcare provider, the beneficiary’s name, the date of service, location of service, type of service, the appropriate HCPCS code, and the proper diagnostic code. A completed CMS-1500 claim form must identify with specificity the healthcare service or product that has been provided to the patient and the dates of service. A blank CMS-1500 claim form is available for review online at <https://www.cms.gov/Medicare/CMS-Forms/CMuasS-Forms/Downloads/CMS1500.pdf>.

68. Defendant Zoll has submitted a separate CMS-1500 claim form to Medicare for each of the thousands of ongoing monthly rentals of its LifeVests for which Zoll has falsely requested payment.

69. Critically, each and every CMS-1500 claim form also contains a certification that must be signed by the healthcare provider in order for Medicare to pay the claim. This certification, among other things, states: “I certify that the information provided is true, accurate, and complete”; that “I have familiarized myself with all applicable laws, regulations, and program instructions”; that “this claim, whether submitted by me or on my behalf by my designated billing company, complies with all Medicare and/or Medicaid laws, regulations, and program instructions for

² The original CMS-1500 claim form was a paper copy (which is still in use) but over the years CMS has adopted electronic equivalents, such as the 837P electronic form, which contain all of the same requirements and certifications as the original CMS-1500. For ease of reference, the Complaint will use the phrase “CMS-1500” to refer to the original paper claim form and all of its electronic equivalents.

payment including but not limited to the Federal anti-kickback statute”; and that “the services on this form were medically necessary.”

70. Upon receipt of a properly completed and certified CMS-1500 claim form, CMS reimburses Medicare providers with payments taken from the Medicare Trust Fund, a Government account supported by American taxpayer money. CMS does not handle the reimbursements itself; rather, it contracts with fiscal intermediaries, private non-governmental entities called Medicare Administrative Contractors (“MACs”), who act as agents of CMS and the Federal Government. The MACs review, approve, and ultimately pay the claims for reimbursement submitted by healthcare providers. 42 U.S.C. § 395h; 42 C.F.R. §§ 421.3 and 421.100.

71. Furthermore, healthcare providers who wish to legally obtain reimbursement from Medicare have a duty to be knowledgeable of, and abide by, all applicable Medicare statutes, regulations, and guidelines. 42 C.F.R. § 424.516(a)(1); 1320a-7b(a)(1) & (2); 1320a-7; 1320a-7a. The applicable rules and regulations include, but are not limited to, the following:

- a. Only bill Medicare for reasonable and necessary products and services. 42 U.S.C. §§ 1395y(a)(1)(A) and (B);
- b. Do not make false statements or misrepresentations of material facts in connection with requests for payment. 42 U.S.C. §§ 1320a-7b(a)(1) and (2); 1320a-7; 1320a-7a;
- c. Be able to provide evidence that the product or service given to the patient is reasonable and necessary. 42 U.S.C. §§ 1320c-5(a)(3); and
- d. Certify, when presenting a claim for reimbursement, that the service provided is reasonable and necessary. 42 U.S.C. § 1395n(a)(2)(B).

72. Just like the Medicare program, the other Government Funded Healthcare Programs at issue in this case all have the same or similar rules, regulations, and requirements for *participation* in their programs and for *reimbursement* of their claims as those described above. See Complaint at paras. 58–71. Most importantly, all of the other Government Funded Healthcare

Programs require, just like Medicare, that the product or service for which reimbursement is sought must be *reasonable and necessary*.³

73. Defendant Zoll, during the relevant time period, has submitted to Medicare many thousands of requests for reimbursement for ongoing monthly rentals of its LifeVest using Medicare's CMS-1500 claim form. Zoll has also submitted many additional thousands of requests for reimbursement for the ongoing rental of its LifeVest to the other Government Funded Healthcare Programs at issue in this case using a claim form identical or similar to the CMS-1500 claim form. *With respect to all of these many thousands of requests for reimbursement from the Government Funded Healthcare Programs, Defendant Zoll has certified that the ongoing monthly rentals of its LifeVests meet Medicare's statutory requirement that the product be reasonable and necessary.* For all of the reasons alleged below and throughout the Complaint, most of these certifications for ongoing monthly rentals are knowingly false. In short, the claims are false because Zoll submitted these claims for ongoing monthly rentals when Zoll knew, or acted in reckless disregard or deliberate ignorance of the truth, that the patient had not actually used Zoll's LifeVest during the relevant time periods – conclusive evidence that the LifeVests were not reasonable and necessary – but Zoll billed the Government for those rental periods anyway.

V. SPECIFIC ALLEGATIONS OF FRAUD

74. Below, the Complaint first explains the disease at the center of this case, sudden cardiac arrest, and the medical standard of care for its treatment and prevention. *See paras 75–96.* The Complaint then describes the specific medical device at issue in this case: Zoll's wearable cardioverter defibrillator distributed under the brand name LifeVest. *See paras. 97–114.* The Complaint then lays out the Government's specific rules for coverage and conditions of payment for ongoing monthly rentals of Zoll's LifeVest. *See paras. 115–138.* Thereafter, the Complaint alleges in detail how Zoll routinely and systematically violates the Government's requirement that ongoing monthly rentals of DME items must be reasonable and necessary when it submits claims

³ The Medicaid and TRICARE programs use the same CMS-1500 claim form as the Medicare program does.

for its LifeVest with knowledge of patients' non-usage, including a discussion of Relator's evidentiary support and conduct by Zoll that exacerbates its false billing scheme. *See* paras. 139–234. Finally, the Complaint explains how Zoll's violations of the FCA lead to substantial patient harm. *See* paras 235–241.

A. Sudden Cardiac Arrest: The Deadly Disease at the Center of this Case

1. The Definition and Causes of Sudden Cardiac Arrest

75. Sudden cardiac arrest (“SCA”), also known as sudden cardiac death (“SCD”) is a sudden, unexpected loss of heart function leading to an immediate cessation of breathing and consciousness. If left untreated, death will occur within minutes. SCA results from a problem with the heart's electrical system: a problem which disrupts the heart's pumping action causing an abrupt stoppage of blood throughout the body. SCA is one of the most frequent causes of death in the United States. It kills over 325,000 people per year.

76. SCA is not the same as a heart attack (known in the medical field as a myocardial infarction). A heart attack occurs when a blocked coronary artery prevents blood from flowing to a particular part of the heart. The lack of blood, and the oxygen it carries, damages the heart muscle in the area surrounding the blockage causing the heart to cease beating properly. SCA, on the other hand, occurs when the heart's electrical system malfunctions causing the heart to beat extremely abnormally.

77. The vast majority of SCAs are caused by abnormal heart rhythms called arrhythmias. The most common life-threatening arrhythmia linked to SCA is ventricular fibrillation, an erratic, disorganized firing of electrical impulses within the ventricles (the heart's lower chambers which pump blood to the brain, lungs, and the rest of the body). Fibrillation results in a trembling of the ventricles rather than a synchronized contraction and is almost always preceded by an abnormally fast heartbeat called tachycardia. When fibrillation occurs, the heart is unable to pump any blood at all.

78. Life-threatening arrhythmias that lead to SCA almost always develop in people with a preexisting heart condition. By far the two most common of these preexisting heart

conditions, also known as risk factors for SCA, are 1) a previous heart attack and 2) coronary artery disease (“CAD”). Patients who survive an SCA are also at extreme risk of experiencing another SCA.

79. Fully 75 percent of all instances of SCA are linked to a previous heart attack. That is because when a person survives a myocardial infarction, the coronary artery blockage that led to the heart attack can also trigger ventricular fibrillation and thus SCA, often in the days and weeks following a heart attack. In addition, a heart attack may leave permanent scar tissue in a patient’s heart. Over time, the scar tissue can cause electrical short circuits which lead to abnormalities in the heart’s rhythm. Such abnormalities are another leading cause of SCA. Accordingly, in both the short and long term, a previous heart attack is an extremely high-risk factor for developing SCA.

80. The other most common risk factor for SCA is CAD, a condition in which the heart’s coronary arteries have become clogged with cholesterol and other deposits which reduce blood flow to the heart. The reduced blood flow adversely affects the heart’s electrical impulses leading to arrhythmias and SCA. Since CAD is also the leading cause of heart attacks, together, these two risk factors – a previous heart attack and CAD – are responsible for the vast majority of all cases of SCA.⁴

2. The Medical Standard of Care for the Treatment and Prevention of SCA

81. Unless emergency treatment is begun immediately, within minutes, SCA quickly leads to death. Emergency treatment includes cardiopulmonary resuscitation (“CPR”) and the use of an external (or internal) defibrillator. CPR keeps enough oxygen in the lungs and gets it to the brain until the normal heart rhythm can be restored with an electric shock to the chest, a process called defibrillation.

⁴ For a further explanation of SCA, see: <https://my.clevelandclinic.org/health/diseases/17522-sudden-cardiac-death-sudden-cardiac-arrest>; and <https://www.mayoclinic.org/diseases-conditions/sudden-cardiac-arrest/symptoms-causes/syc-20350634>

82. Defibrillation is performed by a medical device called a defibrillator which sends an electric shock to the heart. External defibrillators send the shock through paddles placed on the patient's chest. Internal defibrillators are implanted in the patient's chest and deliver the shock from within the body (*see* description of implantable cardioverter-defibrillators or "ICDs" at paras. 89–95). Regardless of the source, the electric shock jolts the heart to enable it to regain function and beat normally. Defibrillators are programmed to recognize when ventricular fibrillation has occurred and send a shock to restart the heart. When used immediately after the onset of SCA, portable external defibrillators (used by emergency personnel in an outpatient setting) and stationary external defibrillators (used by healthcare providers in a facility setting) can save a person's life and reduce further organ damage from oxygen and blood deprivation. For this reason, the use of CPR and defibrillation are the medical standard of care for the treatment of a patient who is actively experiencing an SCA event.

83. For patients at high risk of having a *future* SCA event, including people who have survived a previous heart attack or who have already suffered an SCA, there are a number of effective preventative treatments for SCA. The purpose of these preventative treatments is to get the patient's arrhythmia sufficiently under control to prevent it from developing into fibrillation and SCA. The most frequently used medically accepted preventative treatments for SCA are the following.

84. **Medication.** As a first line of preventative treatment, doctors almost always prescribe anti-arrhythmic drugs to help prevent at risk patients from having an SCA event. By controlling the underlying arrhythmia with medication, the risk of a patient developing SCA can be greatly reduced. Two classes of medication, beta blockers and ACE inhibitors, are commonly used for this purpose. Medication alone can often achieve good heart rhythm control, thus negating the need for an invasive preventative treatment. The use of medication to control a patient's arrhythmia and help prevent SCA is often referred to as "guideline-directed medical therapy," a therapy which is further described below at paras. 98–100.

85. When medication alone is insufficient, an invasive preventative treatment may be necessary, usually in conjunction with the use of anti-arrhythmic drugs as well. The most commonly used invasive preventative treatments are the following.

86. **Coronary angioplasty.** This procedure opens blocked coronary arteries, letting blood flow more freely to the heart. The increased blood flow works to reduce the risk of serious arrhythmias which could lead to SCA. A long, thin tube is passed through an artery, usually in the patient's leg, to a blocked artery in the heart. The catheter is equipped with a special balloon tip that briefly inflates to open the blocked artery. At the same time, a metal mesh stent is often inserted into the coronary artery to keep it open long term, restoring better blood flow to the heart.

87. **Coronary artery bypass graft surgery ("CABG").** Bypass surgery involves sewing veins or arteries into a patient's heart that bypass a blocked or narrowed coronary artery, thus restoring blood flow to the impacted area of the patient's heart. The purpose of the surgery is to improve blood supply within the patient's heart which reduces the risk of serious arrhythmias that could lead to SCA.

88. **Radiofrequency catheter ablation.** This procedure can be used to block a single abnormal electrical pathway within the heart. One or more catheters are threaded through the patient's blood vessels to the interior of the heart. They are positioned along the electrical pathways identified as causing the patient's arrhythmia. Electrodes at the catheter tips are heated with radiofrequency energy. This destroys a small spot of heart tissue and creates an electrical block along the pathway that's causing the arrhythmia thus stopping the arrhythmia and preventing an SCA event.

89. **Implantable cardioverter-defibrillator ("ICD").** Unfortunately, medication and invasive preventative treatments such as those described above sometimes fail to adequately control a patient's arrhythmia. This is a serious problem because such patients continue to suffer from a heart condition which puts them at extremely high risk for SCA. *The vast majority of the patients at issue in this case fall into this extremely high-risk category.* For these patients, the best and most effective medical standard of care is the implantation of an ICD. It is the gold standard

for treating patients who, without implantation of an ICD, would continue to suffer from an extremely high risk of dying from SCA.

90. An ICD is a small battery-powered device similar to a pacemaker that is designed to correct arrhythmias. It is implanted under the skin near the patient's heart in a moderately invasive procedure. One or more electrode-tipped wires from the ICD run through veins to the patient's heart. The ICD *constantly* monitors the patient's heart rhythm. If the ICD detects a rhythm that is too slow, it increases the pace of the heart in the same way that a pacemaker does. When the ICD detects an abnormally fast heart rhythm, known as ventricular tachycardia, the device delivers a small but powerful shock to the heart muscle to reset the heart so that it again beats at a slower, more normal rhythm. An ICD thus protects a patient from ever experiencing an SCA event by correcting an abnormally high heart rate *before* it reaches such a dangerously high level that fibrillation and an SCA event occur. In this way, an ICD is the ultimate preventative treatment for SCA.

91. Moreover, the electrical shock delivered by an ICD is much less powerful than the shock produced by an external defibrillator. External defibrillation requires a great deal of energy (around 3000 volts) to ensure that there is enough electrical energy behind the charge for it to travel through the patient's skin and chest cavity and still be strong enough to deliver a jolt when it reaches the heart that is sufficient to restart a proper heartbeat. Because external defibrillators use such a high voltage, they can only be used on patients who are unconscious. Such a high voltage shock would be dangerous and quite painful if given to someone who is awake and conscious (people who have accidentally received shocks from an external defibrillator while awake describe it like getting kicked in the chest by a mule).

92. On the other hand, an ICD, because it is implanted under the skin, shocks the heart directly through wiring connected straight to the heart. An ICD can thus achieve the same effective shock to get the heart beating properly again with the use of far less energy than external defibrillation requires. For this reason, ICD shocks are often given while the patient is conscious

and awake. People who have received shocks from their ICDs describe them as startling but not painful.

93. Another major difference between ICDs and external defibrillators concerns when the devices are activated. This difference also explains why ICDs, once they are implanted, are much safer and more effective than external defibrillators. ICDs monitor a patient's heart rhythm for a fast heartbeat called ventricular tachycardia, a precursor to possible fibrillation and full blown SCA. When the ICD detects a high level of ventricular tachycardia, it corrects the problem with an electric shock to bring the heartbeat back down to a normal level, while the person is awake and conscious. Thus, ICDs correct ventricular tachycardia before it has a chance to develop into deadly full blown ventricular fibrillation and SCA. For this reason, an ICD, unlike an external defibrillator, is a form of preventative care.⁵

94. In contrast, external defibrillators monitor a patient's heart for signs of SCA, usually ventricular fibrillation (an unorganized quivering or trembling of the ventricles), which means that the person is *already experiencing an SCA event and is close to death*. Since a person whose heart is in fibrillation has no blood pumping to the brain, it is impossible for such a person to be awake and conscious. Such a person will be unconscious and unresponsive. The external defibrillator sends a high voltage charge through the unconscious patient's chest to treat the patient's ongoing SCA. Thus, external defibrillators are a treatment for someone already experiencing a life-threatening SCA. They are not a preventative treatment like ICDs which treat ventricular tachycardia to prevent an SCA from occurring in the first place.

95. In summary, for patients with arrhythmias that cannot be adequately controlled by medication or by one of the invasive preventative treatment options described above, implantation of an ICD is the primary medically accepted preventative treatment option. It is the gold standard

⁵ Of course, in the event a patient with an ICD develops ventricular fibrillation, ICDs can also detect and treat this deadly arrhythmia as well.

of preventative care for high-risk patients because it allows for the patient's uncontrolled arrhythmia to be *constantly monitored and corrected before the onset of a deadly SCA event*.⁶

96. The next section describes and explains the mechanics and uses of the specific medical device at issue in this case: wearable cardioverter defibrillators or WCDs, including Zoll's LifeVest.

B. Wearable Cardioverter Defibrillators: The Medical Device at Issue in this Case

97. A WCD is a wearable garment that contains an external defibrillator. For patients who are at extremely high risk for SCA, a WCD is worn as a safeguard against dying from SCA while they await implantation of an ICD or another long-term preventative treatment for their serious heart condition. The WCD, while being worn by the patient, continuously monitors the patient's heart for signs of SCA and treats the patient with an external shock if the patient develops SCA. A WCD is a temporary safety device to be worn only by patients at high risk for SCA and only until such patients can receive an ICD or other long-term preventative treatment option. The rationale for use of a WCD is straightforward: some, but not all, patients have such a high risk of developing SCA they need to wear an external defibrillator to prevent death from SCA in the interim before having an ICD implanted or another long-term preventative treatment implemented.

98. Doctors usually prescribe WCDs for a maximum period of three months. That is because a WCD is only to be used by qualified patients (only those who meet the criteria for receiving a WCD, *see* criteria below at paras. 122–129) and only on a temporary basis until they can be optimized on guideline-directed medical therapy while awaiting implantation of an ICD. Guideline-directed medical therapy is a term of art in the field of cardiology that refers to treating patients with angiotensin-converting enzyme inhibitors (“ACE”) or angiotensin-receptor blockers

⁶ For a more in-depth discussion of preventative treatment options for SCA, *see* <https://www.mayoclinic.org/diseases-conditions/sudden-cardiac-arrest/diagnosis-treatment/drc-20350640>

(“ARB”), beta-blockers (“BB”), and mineralocorticoid receptor antagonists (“MRA”) which are titrated to maximally tolerated doses for patients at high risk for SCA.

99. The purpose of guideline-directed medical therapy is to use medication to stabilize a patient’s arrhythmia. Doctors prescribe a WCD for a period of three months because the guideline-directed therapy can usually be optimized within three months, often sooner. While the prescription may be for three months, the amount of time that the patient needs the WCD or actually uses the WCD may be less than the full three months.

100. In other words, the recognized standard of medical care for patients awaiting an implantation of an ICD always includes guideline-directed medical therapy: medication intended to stabilize a patient’s arrhythmia prior to receiving an ICD. For patients who qualify for a WCD, doctors may prescribe a WCD *in addition to* the guideline-directed medical therapy because the patient is at an exceptionally high risk of developing SCA while the guideline-directed medical therapy is being optimized and they await implantation of an ICD.

101. Patients who may qualify for a WCD are those at high-risk for SCA who often find themselves in situations where implantation of an ICD or other long-term preventative care is not *immediately* feasible. For example, implantation of an ICD is contraindicated for patients immediately following a heart attack (studies have shown, and physicians generally recommend, that doctors should wait at least 40 days after a patient has had a heart attack, and 90 days if the patient also received angioplasty, before implanting an ICD to allow sufficient time for the patient’s heart to recuperate).⁷ Accordingly, a prime candidate for a WCD is a patient still within the first 40 days following a heart attack who is being released from the hospital. This is someone at high risk for developing SCA who is leaving a facility where the patient had previously had round the clock cardiac care. In this situation, wearing a WCD could provide protection against dying from SCA while receiving guideline-directed therapy and waiting to receive an ICD.

⁷ Gerhard Steinbeck, et al. “Defibrillator Implantation after Myocardial Infarction.” New England Journal of Medicine. 2009 Oct 8; 361; 1427-1436.

102. Similarly, patients at high risk for SCA who have an active infection are not eligible for implantation of an ICD. Such patients must wait until they have recovered from their infection before getting an ICD. In the interim, such patients may also be a good candidate for a WCD. Also, ICDs must be explanted from a patient when a problem arises with the device or the patient develops an infection near the original implantation site. In that situation, a patient may benefit from the temporary use of a WCD while recovering from the explant.

103. Overall, when a WCD is being worn, it is a life-saving device for people at high risk for SCA. *When a WCD is not being worn, it provides no medical benefit whatsoever.*

1. How Zoll's LifeVest Works When It Is Being Worn by a Patient

104. Turning to the mechanics of WCDs, Zoll's product is a vest-like garment with a built-in external defibrillator. To properly use the LifeVest, patients must wear the LifeVest 24 hours a day. It is worn under the clothing and directly against the patient's skin. The only time the WCD should be taken off is when the patient is bathing or showering.

105. Because SCA can happen at any time without warning, the need to wear the LifeVest at all times is crucial. If a patient is not wearing the device, the patient is not using the device as directed by both the manufacturer of the device (Zoll) and by his or her doctor. Here is how Zoll's official website describes how to properly use the LifeVest:

It is critical that you wear the LifeVest at all times – even while you sleep. The only time you should remove your LifeVest WCD is while taking a short shower or bath. This should only be done when someone is home with you, if possible.

https://lifestest.zoll.com/patients/patient-faqs#_FBE0BB8D0C824345A917065A7A07DD8C

106. The U.S. Food and Drug Administration ("FDA") approved what was then called the LifeCor WCD 2000 (the first commercially available WCD) via premarket application approval on December 18, 2001 for "adult patients who are at risk for sudden cardiac arrest and are either not candidates for or refuse an implantable defibrillator." The trade name of the LifeCor WCD 2000 was changed to "LifeVest" in 2002, and the LIFECOR business was acquired by Zoll

in 2006. From 2006 until 2021, Zoll produced the *only* FDA approved WCD on the market in the United States.

107. On August 3, 2021, the FDA granted premarket approval to a second WCD, the Kestra Medical Technologies' ASSURE WCD system. The ASSURE WCD, also a garment like product with a built-in external defibrillator, is a direct competitor to Zoll's LifeVest. Kestra began marketing its WCD in select markets in the fall of 2021.

108. When it is being worn, the LifeVest constantly monitors the patient's heart for extreme ventricular tachycardia and ventricular fibrillation. If it detects one of these life-threatening heart rhythms, the LifeVest sends an electric shock – a high voltage electrical charge identical to the strong charge produced by other types of external defibrillators – to the patient's chest in an attempt to restore a normal heartbeat. Wearing a WCD is like having a paramedic follow a patient around all day and night, ready to shock the patient with defibrillator paddles if the patient develops SCA.

109. Zoll's LifeVest includes an electrode belt that contains both cardiac therapy electrodes and cardiac monitoring electrodes. The cardiac therapy electrodes are designed to deliver an electrical shock when the cardiac monitoring electrodes detect a life-threatening ventricular arrhythmia. The LifeVest also has a built-in system to communicate with the patient through voice messages, tones, and vibrations.

110. If the LifeVest detects extreme ventricular tachycardia or ventricular fibrillation, an alert will sound to determine if the patient is conscious. The device warns the patient and any nearby persons with a loud voice message that the device is preparing to deliver a high voltage shock. The voice instructs the patient to stop the impending shock by pressing a response button. The message tells the patient this – to press the button – because if the person is conscious and able to press the button, then an SCA has not occurred and the button should be pressed to stop the shock from coming. This is because during a real-life SCA event, the brain receives no oxygen which inevitably causes the patient to lose consciousness. If the patient is able to hear the message and turn off the device, then a shock is not needed, so the patient should press the button and a

shock will not be delivered. When the warning alerts a patient of an impending shock and the patient is conscious and awake, it is considered a false alarm because a conscious patient could not be having an SCA. The patient must then hit the response button to stop the device from delivering a shock.

111. If a patient wearing a WCD is unconscious and unresponsive and the device detects a life-threatening arrhythmia, it is virtually certain the person is experiencing an SCA event. In that instance, the alarm will sound and the voice message will be delivered, but the patient is unconscious so he or she will not be able to press the response button to turn off the device. The WCD will then release a gel over the cardiac therapy electrodes located within the vest and a treatment shock will be delivered. The WCD is designed to deliver an electric shock within 60 seconds of the onset of ventricular tachycardia or ventricular fibrillation, unless a conscious patient presses the response button and stops the device. If the first shock does not restore a normal heartbeat, the WCD will deliver another one. This process will repeat for up to five shocks in total.

112. Note too that the LifeVest, when being worn, monitors the patient's heart for both ventricular tachycardia and ventricular fibrillation. It monitors for both conditions because both can lead to a life-threatening SCA.⁸ If a patient experiences ventricular tachycardia but it is not extreme enough to lose consciousness, the WCD will still alert the patient of a pending electric shock and the patient will need to respond by pressing the button to avoid receiving a shock. This need to turn off the device when experiencing milder ventricular tachycardia is one of the reasons the LifeVest produces many false alarms – frightening situations that require the patient to quickly push the button and turn off the device to avoid receiving an extremely painful jolt of electricity.

2. How Defendants Describe their Zoll LifeVest

113. Here is how Defendant Zoll describes its signature product, the Zoll LifeVest, on its official Company website:

⁸ In extreme cases of ventricular tachycardia, the heart beats so fast the ventricles do not have time to fill with blood before contracting, a condition which prevents the heart from pumping any blood at all. This extreme heart rate is physiologically indistinguishable from ventricular fibrillation and, like ventricular fibrillation, causes SCA. Patients who experience such extreme tachycardia leading to SCA must also be treated with an electrical shock from a defibrillator in order to survive.

The LifeVest® wearable cardioverter defibrillator (WCD) is designed to protect patients at risk of sudden cardiac death (SCD), *when a patient's condition is changing and permanent SCD risk has not been established.*

While some defibrillator devices are implanted under the skin, the LifeVest WCD is worn directly against the patient's skin. *It is lightweight and easy to wear, allowing patients to return to most of their daily activities with peace of mind that they have protection from SCD.* LifeVest is designed to detect certain life-threatening rapid heart rhythms and automatically deliver a treatment shock to save a patient's life. . . .

LifeVest is intended to be worn while you are at high risk of sudden cardiac death. ***Most patients will wear the device temporarily, until their heart gets stronger or until a long-term treatment is decided.***

See https://lifestest.zoll.com/patients/patient-faqs#_14536D15C6D5482189881F36FA7198AE (emphasis added) (last visited on October 23, 2022).

114. Similarly, Defendant Asahi Kasei describes the Zoll LifeVest on its official Company website as follows:

Our LifeVest™ Wearable Defibrillator is worn by patients at risk for sudden cardiac arrest (SCA), providing protection during their changing condition and while permanent SCA risk has not been established. ***The LifeVest allows a physician time to assess the patient's long-term arrhythmic risk and make appropriate plans.*** The LifeVest is lightweight and easy to wear, enabling patients to return to their activities of daily living, while having the peace of mind that they are protected from SCA. The LifeVest continuously monitors the patient's heart and, if a life-threatening heart rhythm is detected, the device delivers a treatment shock to restore normal heart rhythm.

See https://www.asahi-kasei.com/services_products/health_care/ (emphasis added) (last visited on October 23, 2022).

C. Medicare's Coverage and Conditions of Payment for Ongoing Monthly Rentals of Zoll's LifeVest

115. By statute, Medicare will only pay for DME rentals that are “reasonable and necessary.” 42 U.S.C. §§ 1395y(a)(1)(A) and (B) (“no payment may be made under [Medicare] part A or part B for any expenses incurred for items or services – (1)(A) which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” or “(B) . . . which are not reasonable and necessary for the prevention of illness.”) As noted above, the requirement that a product or service be

“reasonable and necessary” is one of the bedrock principles of the Medicare program. *See* Complaint at paras. 60–73. When Medicare pays for an *ongoing rental* of a DME item (rather than pays to purchase a DME item for a beneficiary), there are two, separate but equally important, requirements that Medicare follows to determine whether a DME item is reasonable and necessary throughout the rental period: 1) medical eligibility *and* 2) whether the patient *continues to need and continues to use* the DME item.

116. For medical eligibility, the first prong, Medicare looks to the relevant medical eligibility criteria specific to the DME item in question to determine if the product is reasonable and necessary. The medical eligibility criteria for coverage of Zoll’s LifeVest are set out in what Medicare calls a local coverage determination (“LCD”). Generally speaking, the medical criteria contained in an LCD are a proxy for determining whether the product meets the medical eligibility prong of the reasonable and necessary standard. In the present case, the medical criteria found in LCD-L33690 are widely used by Medicare’s MACs (the entities who actually make the determinations and pay the bills for Medicare) to determine whether they will initially cover the rental of a Zoll LifeVest. Below, the Complaint further discusses the application of L33690’s medical criteria to the Zoll LifeVest. *See* Complaint at paras. 122–125.

117. For *ongoing rentals* of DME items, Medicare also looks at the second set of requirements – whether the patient continues to use and continues to need the DME item (the second prong) – to determine if the product continues to be reasonable and necessary throughout the rental period.⁹ During ongoing monthly rental periods, if the patient continues to need the DME item and continues to use the DME item, Medicare will continue to pay for the ongoing rental because it continues to be reasonable and necessary. On the other hand, if during the ongoing monthly rental periods, the patient no longer needs or no longer uses the DME item, then Medicare

⁹ When a DME item is initially rented to a patient, Medicare only looks at the medical eligibility criteria (the first prong of the two requirements) to determine whether the item is reasonable and necessary for the first month. The second prong – continued use and continued need – is not relevant because the patient has obviously not yet had the opportunity to use the product.

will not continue to pay for the rented item because Medicare considers the DME item to no longer be a reasonable and necessary medical benefit.

118. Medicare refers to this condition of payment as the “continued use” requirement and it applies to the rental of *all* DME items, not just WCDs. Put simply, Medicare will not continue to pay rent for a DME item that a patient is not using. This is not complicated; it is simple common sense. No insurer, including the Government, will continue to pay rent for an item that a patient is not using. If the patient stops using the device, then Medicare stops paying for the device.

119. The policy underlying the “continued use” payment rule is straightforward too: if a patient is not using a prescribed DME item, then it is a self-evident fact, *i.e.*, conclusive evidence, that the DME item is not reasonable and necessary medical care ***for that particular patient at that particular time***. It is certainly not reasonable and necessary for the Government to spend taxpayer money on a DME item that a patient is not using. This is the reason Medicare will not pay for an ongoing rental when a patient is not using the product. The Complaint provides a further discussion of the rules and regulations regarding patient non-usage and ongoing monthly rentals, as applied to Zoll’s LifeVest, at paras. 130– 138.

120. By way of illustration, the Relator notes that the Government has applied the continued use payment rule, as well as the reasonable and necessary standard, in a situation similar to the present case. In its December 2020 settlement with Apria Healthcare Group, Inc. and Apria Healthcare, LLC, the Department of Justice (“DOJ”) stated that “[i]t is critical to the financial integrity of federal health programs like Medicare and Medicaid that reimbursements are made only for medically necessary items and services,” noting that Apria “continued to seek payments from federal health programs for NIV rentals ***each month even though its [respiratory therapists] frequently failed to conduct in-home visits to verify that patients were still using their NIVs.***” (emphasis added). DOJ Press Release, December 21, 2020. “*Acting Manhattan U.S. Attorney Announces \$40.5 Million Settlement with Durable Medical Equipment Provider Apria Healthcare for Fraudulent Billing Practices,*” found at <https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-405-million-settlement-durable-medical-equipment>.

121. The allegations in the present case are arguably even stronger than those in the *Apria* matter. Here, Zoll already has a system in place that tracks and records the LifeVest usage and non-usage for all of its patients. Through this system, Zoll knows that a high percentage of its patients are not using their LifeVests; Zoll knows which patients are not using their LifeVests, and despite this knowledge, Zoll still bills the Government for the ongoing monthly rentals anyway. *See* Complaint at paras. 139–163.

1. Medicare’s Medical Eligibility Criteria for Coverage of Zoll’s LifeVest¹⁰

122. LCD-L33690, entitled “Automatic External Defibrillators,” lays out Medicare’s medical eligibility criteria for coverage of the Zoll LifeVest. In general terms, L33690 says that Medicare will cover a WCD for patients who have previously had an SCA event; patients with an inherited predisposition to having an SCA event; patients who are post-myocardial infarction (*see* Complaint at paras. 78–79, 101, and 171–177 for a further explanation of this important factor), or patients who are having an ICD removed.

123. The relevant section of L33690 is quoted below in full:

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Automatic external defibrillators are covered for beneficiaries at high risk for sudden cardiac death (SCD) due to one of the conditions described under Parts I or II below. It is expected the treating practitioner be experienced in the management of beneficiaries at risk for SCD.

Part I. A wearable defibrillator (K0606) is covered for beneficiaries if they meet one of the criteria (1-4), described below:

1. A documented episode of ventricular fibrillation or a sustained, lasting 30 seconds or longer, ventricular tachyarrhythmia. These dysrhythmias may be either spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause

¹⁰ This is the first prong – medical eligibility – of the two sets of requirements for meeting the reasonable and necessary standard when renting a LifeVest on an ongoing basis. Continued need and continued use, the second prong, are discussed in the next section of the Complaint. *See* Complaint at paras. 130–138.

and not occur during the first 48 hours of an acute myocardial infarction; or

2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy; or
3. Either documented prior myocardial infarction or dilated cardiomyopathy and a measured left ventricular ejection fraction less than or equal to 0.35; or
4. A previously implanted defibrillator now requires explantation. Refer to the ICD-10 Codes section in the LCD-related Policy Article for applicable diagnoses.

Refer to the ICF-10 Codes section in the LCD-related Policy Article for applicable diagnoses.

See <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33690>

124. To clarify, note that L33690 applies to the coverage of all automatic external defibrillators, of which there are two kinds: wearable and nonwearable. L33690, Part I, which is quoted above, addresses coverage for “wearable defibrillators,” also known as WCDs: the subject matter of this Complaint. L33690, Part II, which is not quoted above, covers “nonwearable automatic defibrillators,” a product similar to the portable defibrillators used by paramedics in the field but designed for personal use by Medicare beneficiaries and their families. Zoll is also a leading manufacturer of non-wearable automatic defibrillators as well as WCDs. However, this Complaint does not make any allegations regarding non-wearable automatic defibrillators. The only DME item at issue in this Complaint is the Zoll LifeVest, a WCD, whose medical eligibility criteria are laid out in L33690, Part I.

125. Relator does not challenge whether Zoll patients who have been prescribed a LifeVest initially meet the medical eligibility criteria laid out above in L33690, Part I, *see* Complaint at paras. 122–123, when they first receive a LifeVest. On the contrary, Relator alleges that these are extremely sick patients who would benefit from wearing a WCD until they receive an ICD or another method of long-term preventative care. Relator includes a discussion of the medical eligibility criteria here because it allows for a fuller picture of both the product and the patients at the center of this case and because it shows how truly ill these patients really are.

Patients who meet the medical criteria laid out in L33690, Part I for initial use of a Zoll LifeVest are critically ill; they are at the highest risk level for succumbing to SCA. If these patients do not wear the Zoll LifeVest, they need immediate medical attention to protect them from dying from SCA. *See* Complaint at paras. 77–95. Relators do allege, however, that Zoll should stop billing the Government for the LifeVests when these patients stop using their LifeVests. *See* Complaint at paras. 139–247.

126. The HCPCS billing code for the Zoll LifeVest is HCPCS Code K0606, appropriately entitled “Automatic external defibrillator, with integrated electrocardiogram analysis, garment type.” *See* description on cms.gov at: <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52458#:~:text=Wearable%2C%20automatic%2C%20external%20defibrillators%20with,coded%20using%20HCPCS%20code%20K0606>

127. As a DME manufacturer and supplier enrolled in Medicare, Zoll may bill Medicare directly, under HCPCS Code K0606, for a patient’s *use* of its LifeVest. Under K0606, Medicare reimburses Zoll on a monthly basis for the rental of the LifeVest. Medicare does not purchase the LifeVest for its members because it is extremely expensive and is intended to be used only on a temporary basis. Under K0606, Medicare’s average reimbursement rate for the LifeVest varies from region to region. The rate, however, generally falls in the range of \$2,000 to \$3,000 per month. Because it is a rental, when the patient is no longer using the LifeVest, the device must be returned to Zoll.

128. In addition, Medicare requires, pursuant to LCD-L33690, that a healthcare provider provide Zoll with a prescription for the LifeVest before the Company can submit a claim to Medicare for reimbursement.

129. Furthermore, because it is a monthly rental item, Zoll must submit a separate signed and certified CMS-1500 claim form for each month that it rents a LifeVest to a patient. Each one of these claim forms states, among other things, the name of the patient, the relevant HCPCS Code (K0606), and the time period (a month at a time) for which Zoll rents a LifeVest to the patient for the patient’s use. For each claim form, Zoll must also sign a certification which swears to the

accuracy of the information in the claim form and that the rental meets all of the Government's rules and regulations, including that the LifeVest be reasonable and necessary. *See* Complaint at paras. 67–73.

2. *Continued Need and Continued Use: Medicare's Conditions of Payment for Ongoing Monthly Rentals of Zoll's LifeVest*¹¹

130. LCD-L33690, also states, under the heading “Coverage Guidance” for WCDs, the following:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) ***be reasonable and necessary*** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) ***meet all other applicable Medicare statutory and regulatory requirements***.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- **The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.**
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

See the entire text of LCD-L33690 on the cms.gov website at <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33690> (emphases added above).

131. The second paragraph of the quote above refers to the ““reasonable and necessary” criteria” that must be met for Medicare to cover a WCD. This is a direct reference to the medical eligibility criteria which the Complaint discusses above at paras. 115–116 and 122–125.

¹¹ This is the second prong of the two sets of requirements that must be met to establish that an ongoing monthly rental of a LifeVest meets the reasonable and necessary standard throughout the rental period.

Thereafter, the text of L33690 goes on to instruct healthcare providers that in addition to meeting the medical eligibility criteria, “there are other payment rules, which are discussed in the following documents, that *must also be met* prior to Medicare reimbursement.” L33690 then identifies one of those “following documents” as “The LCD-related Standard Documentation Requirements Article” which is “located at the bottom of this policy.” The document “located at the bottom of this policy” is a well-known Medicare document entitled “A55426: Standard Documentation Requirements for All Claims Submitted to DME MACs.” All LCDs for rentable DME items contain this same instruction from CMS: that claims for reimbursement of rented DME items must not only meet the LCD’s “reasonable and necessary” medical eligibility criteria but they must also meet the requirements for payment laid out in Article A55426.

132. The relevant sections of Article A55426, “Standard Documentation Requirements for All Claims Submitted to DME MACs,” are quoted below in full:

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this timeframe. Entries in the beneficiary’s medical record must have been created prior to, or at the time of, the initial DOS to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rented DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary’s medical record to support that the item continues to remain reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order/prescription by the treating practitioner for refills;
- A recent change in an order/prescription;
- A properly completed CMN or DIF with an appropriate length of need specified;

- **Timely documentation in the beneficiary's medical record showing usage of the item.**

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rented item by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. **Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.**

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. *Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:*

- **Timely documentation in the beneficiary's medical record showing usage of the item,** related option/accessories and supplies;
- Supplier records documenting the request for refill/replacement of supplies in compliance with the REFILL DOCUMENTATION REQUIREMENTS section. This is deemed sufficient to document continued use for the base item, as well;
- **Supplier records documenting beneficiary confirmation of continued use of a rental item.**

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

See the entire text of Article A55426 on the cms.gov website at: <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55426&ver=91&> (emphases added above).

133. Thus, under LCD-L33690, Medicare will only pay for ongoing monthly rentals of a WCD if both the medical eligibility criteria laid out in L33690 have been met (*see* the preceding section of the Complaint) *and* the payment rules laid out in “Article A55426: Standard Documentation Requirements for All Claims Submitted to DME MACs” have been met (the rules requiring “Continued Medical Need” and “Continued Use”).

134. A55426 establishes two categories of payment rules that apply specifically to the reimbursement of ongoing rentals of DME items. These two categories are “*continued medical*

need” and “continued use.” First, with respect to “continued medical need,” A55426 states that, when dealing with a claim for an ongoing rented DME item, “there must be information in the beneficiary’s medical record to support that the item continues to remain reasonable and necessary.” An example of the type of “documentation justifying continued medical need,” according to A55426, is ***“timely documentation in the beneficiary’s medical record showing usage of the item.”***

135. Second, under A55426, Medicare defines “continued use” as “the ongoing ***utilization*** of . . . a rented item by a beneficiary.” In the document, CMS then proceeds to state explicitly that the burden of proving “continued use” falls on the DME supplier (here, it is Zoll) and that the DME supplier must not bill Medicare when the patient is no longer using the DME supplier’s rented DME item. A55426 could not be any clearer on this point: 1) ***“Suppliers are responsible for monitoring utilization of DMEPOS rental items”*** and 2) ***“Suppliers must discontinue billing Medicare when rental items . . . are no longer being used by the beneficiary.”***

136. A55426 goes on to state that records from either the patient or the DME supplier may be used to “confirm” that the patient “continues to use” the rented DME item. A55426 then provides examples of the type of documentation that may be used to show “that an item submitted for reimbursement continues to be used by the beneficiary,” including ***“timely documentation in the beneficiary’s medical record showing usage of the item”*** and ***“supplier records documenting beneficiary confirmation of continued use of a rental item.”***

137. In summary, when a DME supplier submits a claim for reimbursement for an ongoing rental of a DME item, there must be information in the medical record to support that the item *continues* to meet the statutorily required “reasonable and necessary” standard throughout the rental period. To facilitate the enforcement of this statutory requirement, Medicare has adopted two payment rules for the reimbursement of an ongoing monthly rental of a DME item: that the beneficiary *continues to need* and *continues to use* the rented DME item. ***To meet these payment rules, all that the DME supplier needs to provide Medicare is either “timely documentation in***

the beneficiary’s medical record showing usage of the item” or “supplier records documenting beneficiary confirmation of continued use of a rental item.”

138. Therein lies the problem for Zoll. As described more fully in the next section of the Complaint, *see paras. 139–163*, the beneficiaries’ medical records and Zoll’s own records show precisely the opposite: most of Zoll’s patients do not *continue to use* their LifeVests but Zoll continues to bill the Government Funded Healthcare Programs for the LifeVests anyway. Zoll maintains contemporaneous detailed electronic user records for every patient who receives a Zoll LifeVest. These records reveal that for a majority of the CMS-1500 claim forms that Zoll submits to the Government Funded Healthcare Programs for reimbursement of ongoing monthly rentals of its LifeVest, the patient did not continue to use Zoll’s LifeVest. In actuality, many patients are thoroughly non-compliant.¹² Each one of these thousands upon thousands of claims for reimbursement of non-used LifeVests is knowingly false, in violation of the FCA, because Zoll knew that continuing to submit bills for these non-used LifeVests did not meet Medicare’s reasonable and necessary standard.

D. Zoll Routinely and Systematically Violates Medicare’s Requirement that Ongoing Monthly Rentals of DME Items Be Reasonable and Necessary When It Submits Claims for Its LifeVests with Knowledge of Patients’ Non-Usage

139. Zoll has an excellent system for closely and continuously monitoring patient usage of its LifeVests. The system is a computer application called the Zoll Patient Management (“ZPM”) network (before ZPM, Zoll had another system called the LifeVest network which also closely and continuously monitored patient usage). Whenever a patient puts on a LifeVest, the WCD immediately begins to monitor the patient’s heart; it also records various types of cardiac-related data, and automatically transmits all of the information that it collects to the ZPM application. The recorded information includes the exact time the patient began wearing the

¹² Throughout the Complaint, the Relator interchangeably (and often) uses the words “non-usage” and “non-compliant” to describe the same conduct: patients who have completely stopped using their LifeVest for consecutive days, weeks, or months at a time.

LifeVest. Whenever a patient takes off the LifeVest, the device stops monitoring and recording cardiac data, and the ZPM notes the exact time the patient stopped wearing the LifeVest.¹³

140. Accordingly, Zoll has an electronic record of the exact dates and times that every one of its patients uses his or her LifeVest. This record goes back to at least the year 2017, when Relator began working at Zoll, and probably further. Anyone who works at Zoll, including the COPAs, TMs, RMs, technical support representatives, and Account Coordinators, has access to the ZPM and its patient information. Despite this access, Zoll has a policy that no one at Zoll needs to, or should attempt to, verify if a patient has been using the LifeVest before billing Medicare for an ongoing monthly rental of the device. *See* Complaint at paras. 187–191; *see also* Complaint at paras. 198–234 (discussion of what Relator refers to as Zoll’s “Don’t Ask, Don’t Tell” policy regarding patients’ non-usage of its LifeVests.)

1. Zoll’s “Wear Time Histogram” Charts: Patient Examples

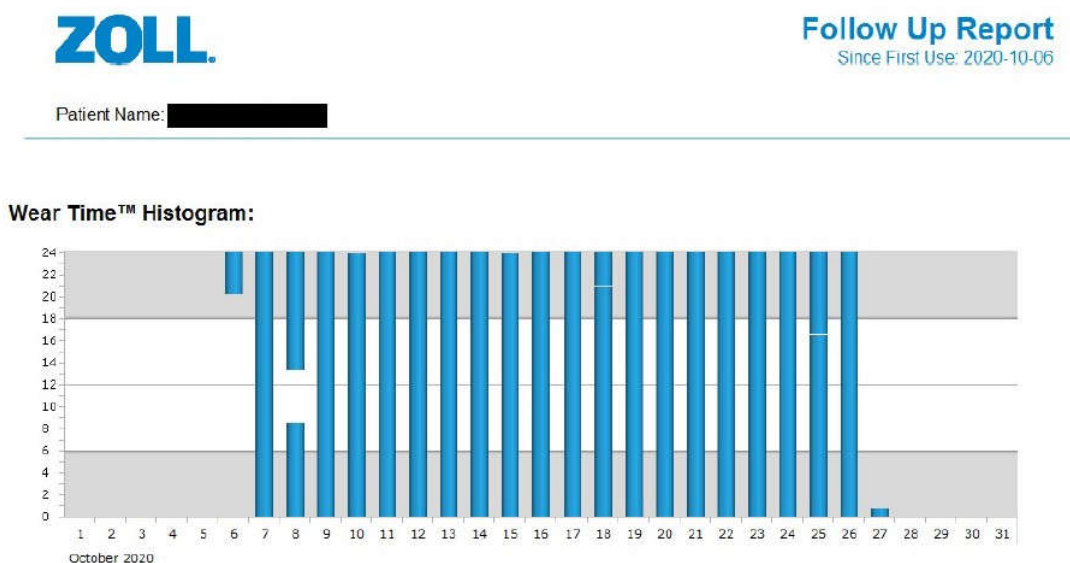
141. The ZPM system can display the patient data it receives from the LifeVest in several different kinds of charts. Zoll calls one such chart a “Wear Time Histogram.” It is an easy-to-read bar graph which reflects the exact dates and times a patient has worn his or her LifeVest. Below, at paras. 142–154, the Complaint provides the Wear Time Histograms for seven sample patients. The Relator chose these patients at random from the ZPM database as examples of typical patterns of patient usage, and non-usage, of the Zoll LifeVest. The seven Wear Time Histograms, and the data contained in the seven Histograms, all come directly from Zoll’s ZPM database. Overall, Zoll’s ZPM system contains many thousands of patients with Wear Time Histograms similar to the patient examples included in the Complaint.

142. **Patient FGP.** Below is Zoll’s Wear Time Histogram for Patient FGP, a Medicare beneficiary, that shows when Patient FGP used and did not use the Zoll LifeVest. The blue bars represent times the patient wore the LifeVest. A gap between the bars within a particular day

¹³ In addition to patient usage of the LifeVest, when a patient is wearing a LifeVest the ZPM records other categories of data, including ECG reports, the Heart Rate Trend, the patient’s Daily Activities (to know if the patient is active or inactive due to their health condition), in what position the patient sleeps (inclined, totally horizontal, factors that tell if the patient has shortness of breath), as well as data that indicate possible heart failure.

represents periods of time during that day when the patient did not wear the LifeVest. Days on the chart without any colored bars represent entire days that the patient did not wear the LifeVest.

143. The Wear Time Histogram for Patient FGP shows that the patient put on the LifeVest for the first time around 8 p.m. on 10/06/20; Patient FGP then wore the LifeVest until approximately 8 a.m. on 10/08/20; at which time, Patient FGP took off the LifeVest for about 4 hours; Patient FGP then put the LifeVest back on around 2 p.m. on 10/08/20; Patient FGP then wore the LifeVest pretty much continuously until approximately 1 a.m. on 10/27/20, thereafter Patient FGP never wore the LifeVest again. Thus, according to Zoll's own records, Patient FGP used the LifeVest for 19 full days and 3 partial days, all within the month of October 2020.



144. Relator and her counsel also examined other records maintained by Zoll (not the ZPM database) to determine the total number of months that Zoll billed Medicare, as well as the total reimbursement amount that Medicare paid Zoll, for Patient FGP's rental of Zoll's LifeVest. *That examination revealed that Zoll billed Medicare for six months of rent and Medicare paid Zoll a total of \$12,761.88 to rent a LifeVest for Patient FGP.*

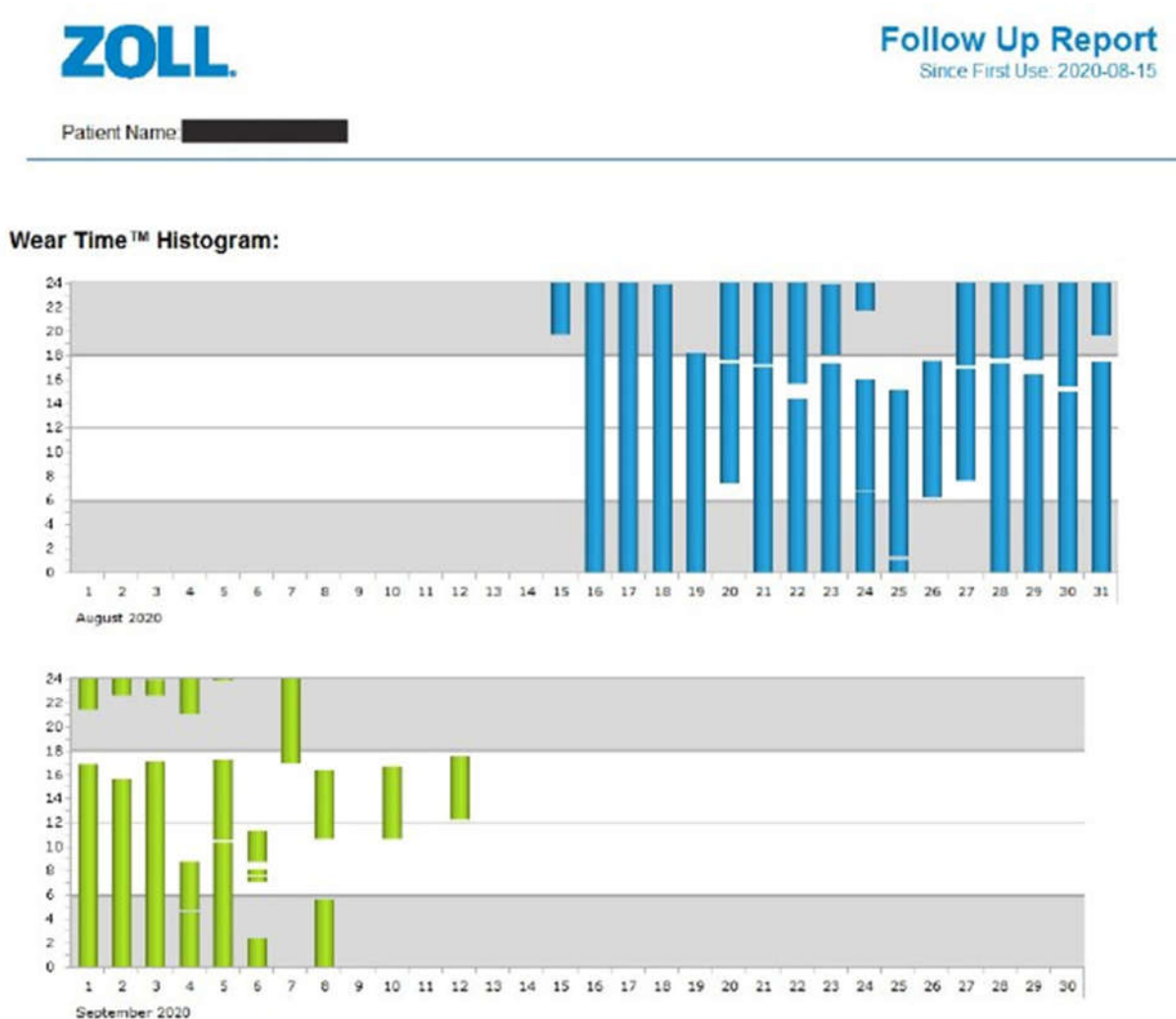
145. In addition to Patient FGP, Relator and her counsel performed a similar examination of Zoll's records (ZPM and non-ZPM) with regard to 49 additional patients. Below,

at para. 156, the Complaint sets out a chart prepared by Relator and her counsel that shows the results of that examination. The chart lists each patient's usage of the LifeVest (in number of days, taken from the ZPM database), the total number of months Zoll billed Medicare, and the total dollar amount that Medicare paid Zoll for 50 different sample patients (the "Patient Usage, Billing, and Reimbursement Chart" or the "Chart"). The Chart includes, as the first entry, the information identified above for Patient FGP (the six other patient examples that are analyzed in this section of the Complaint are also included in the Chart).

146. Based upon Relator's almost five years of firsthand observation and experience working at Zoll, as well as the many meetings and communications that Relator had over the years with other Zoll employees located all over the country, Relator alleges that Patient FGP's pattern of use is typical of a substantial percentage of all Zoll patients. As with Patient FPG, many Zoll patients start out wearing the LifeVest somewhat regularly, but after a short period of time, their use slows down and they completely stop wearing the LifeVest sometime within, or shortly after, the first month of renting the device. *See Complaint at paras. 164–177 for a discussion of the many reasons for Zoll's patient non-usage problem. Relator also alleges that, as with the typical situation represented by Patient FGP, Zoll almost always continues to bill the Government Funded Healthcare Programs for one or more (usually more) ongoing monthly rental periods **after the patient has completely stopped using the LifeVest.***

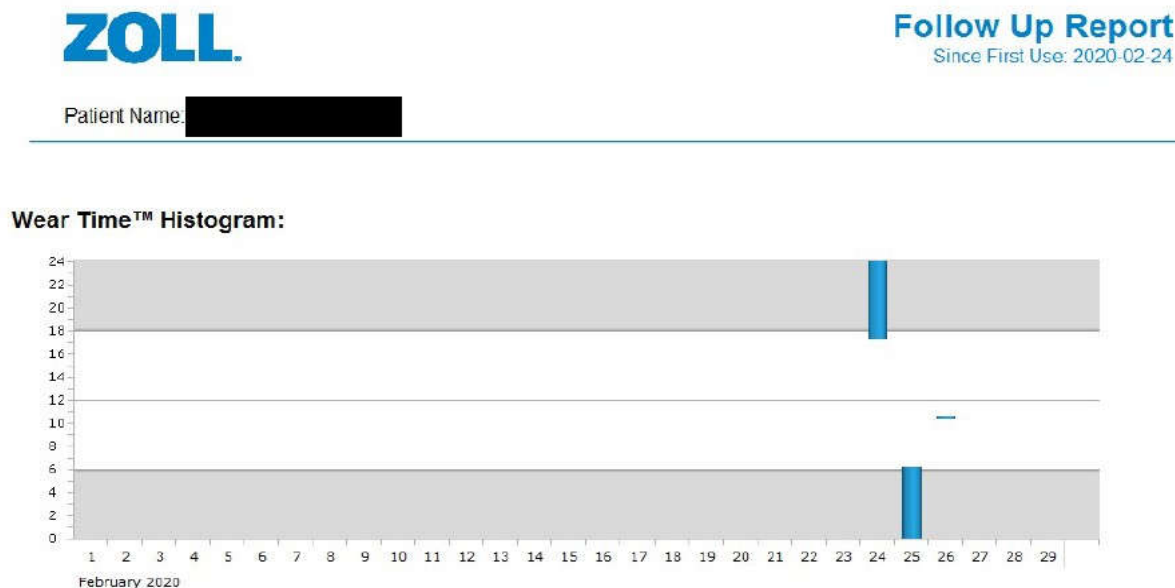
147. **Patient MCH.** For example, below is Zoll's Wear Time Histogram for Patient MCH, a Medicare beneficiary. The ZPM data shows that Patient MCH wore the LifeVest for sporadic periods of time each day over approximately 29 consecutive days: from 8/15/20 to 9/12/20 (2 full days, and 25 partial days). After the first month, Patient MCH never used the LifeVest again. Despite this, *Zoll billed Medicare for three months of rent and Medicare paid Zoll a total of \$14,062.52 to rent a LifeVest for Patient MCH.* According to Relator, Patient MCH's Wear Time Histogram is also typical of the pattern of use, and non-use, of many Zoll patients. Sporadic use within a single day is common, as it was for Patient MCH, because some patients find it difficult to wear the LifeVest for 24 hours in a row. Plus, as noted above, a high percentage

of Zoll patients, like Patients MCH and FGP, simply stop wearing the LifeVest after a few weeks.¹⁴ For these many thousands of patients with patterns of use, and non-use, similar to Patients MCH and FGP (what Relator alleges is the most common pattern of non-usage at Zoll), the Company continues to bill Medicare for ongoing monthly rentals even though the patients have completely stopped wearing the LifeVest.



¹⁴ The color of the bars in Zoll's Wear Time Histogram charts changes each month between blue and green (even months are blue, odd months are green). That is why, in Patient MCH's chart, the bars are blue in the month of August and switch to the color green in the month of September. The change in color is only there to make it easy to tell when a new month begins. The color of the bars has no other significance.

148. **Patient MSO.** Below is Zoll's Wear Time Histogram for Patient MSO, a Medicare beneficiary. Zoll's ZPM data reveals this patient wore the LifeVest for only a portion of three consecutive days: 2/24, 2/25, and 2/26/20, and then never wore the device again. Despite Patient MSO's almost non-existent use of Zoll's LifeVest, *Zoll billed Medicare for three months of rent and Medicare paid Zoll a total of \$11,953.96 to rent a LifeVest for Patient MSO.*



149. According to the Relator and Zoll's own records, Patient MSO's extreme pattern of use (only three days) also occurs quite often among Zoll patients, *i.e.*, a substantial number of patients fit this extreme pattern. This is because many patients, even though they are so ill they meet the medical eligibility criteria found in LCD-L33690, simply do not like to wear the LifeVest once they receive it. They try it on a few times and find it bulky; it will not fit under clothes; it is sweaty and generally uncomfortable; they are anxious about false alarms, and the patients never wear it again. Despite such extensive non-usage, based upon Relator's experience and Zoll's own records, a majority of the time, with respect to these patients who essentially never wear the LifeVest at all, Zoll still bills *not just for the first month, but for ongoing monthly rentals as*

well. Patient MSO's case is a good example: the patient wore the LifeVest for just a portion of three days during the first month, yet Zoll billed Medicare, and received reimbursement from Medicare, for three full months of rent. Patients SMM, AM, and LRT are three other examples of this extreme pattern of patient non-usage and Zoll's egregious false billing for it.

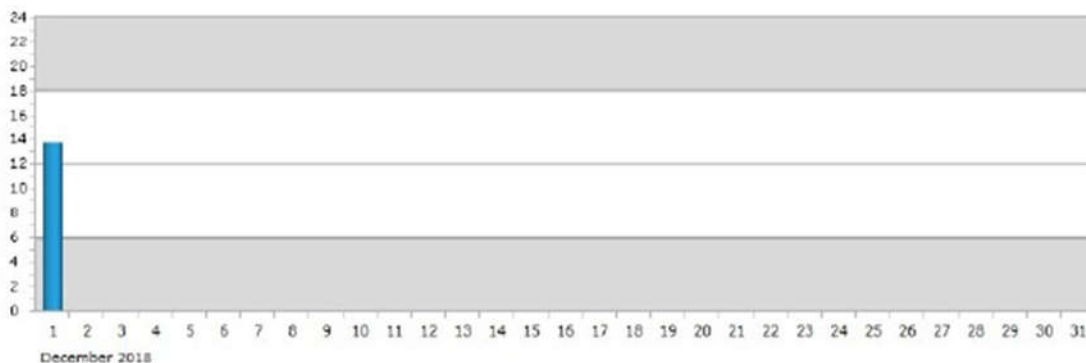
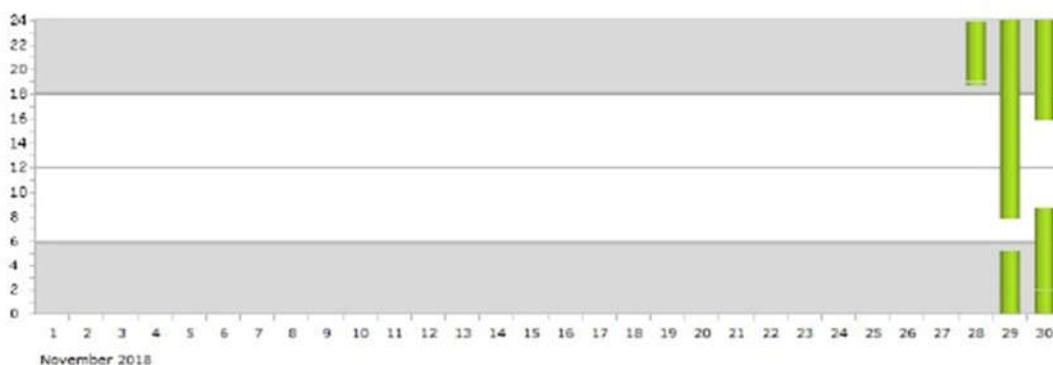
150. **Patient SMM.** Below is Zoll's Wear Time Histogram for Patient SMM, a Medicare beneficiary. Zoll's ZPM data reveal this patient wore the LifeVest for only a portion of four consecutive days: 11/28/18 to 12/01/18, and then never wore the device again. Despite Patient SMM's almost complete non-usage of Zoll's LifeVest, *Zoll billed Medicare for three months of rent and Medicare paid Zoll a total of \$10,500.00 to rent a LifeVest for Patient SMM.*

ZOLL

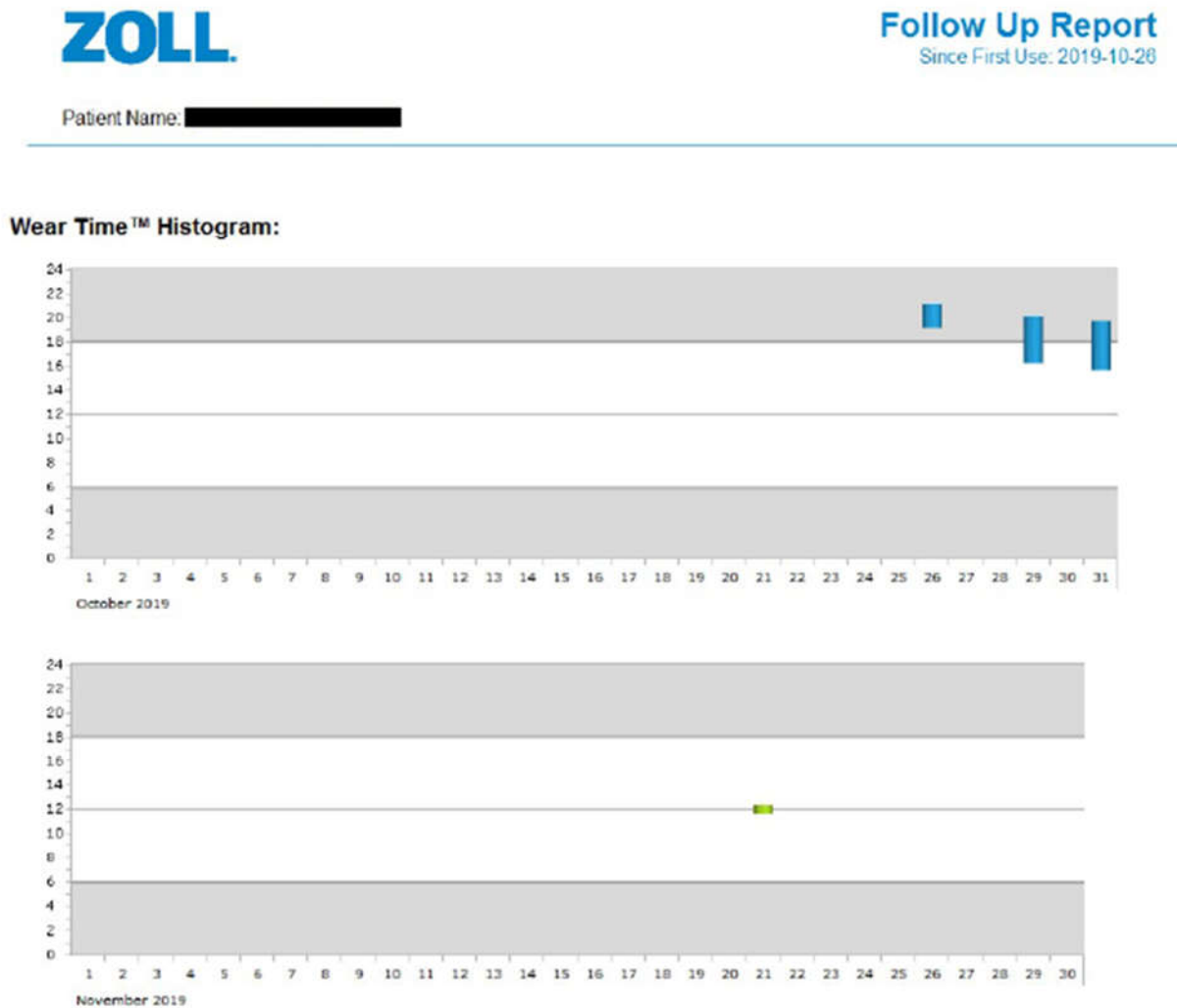
Follow Up Report
Since First Use: 2018-11-28

Patient Name: [REDACTED]

Wear Time™ Histogram:

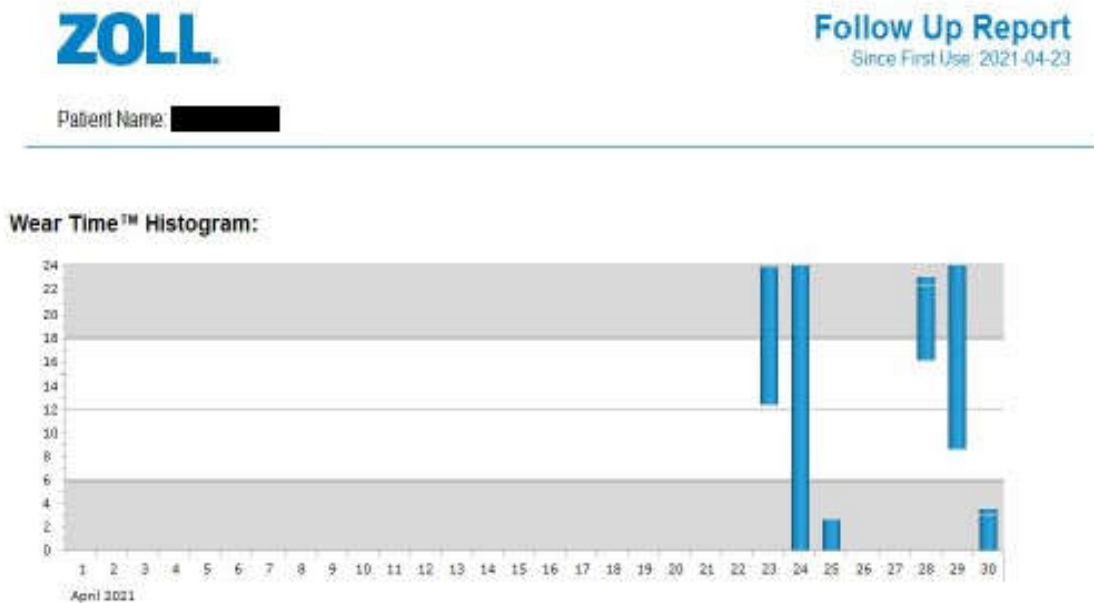


151. **Patient AM**. Below is Zoll's Wear Time Histogram for Patient AM, a Medicare beneficiary. Zoll's ZPM data reveal this patient wore the LifeVest for only a small portion of four separate days spread out in the months of October and November 2019, and then never wore the device again. Despite Patient AM's almost complete non-usage of Zoll's LifeVest, *Zoll billed Medicare for four months of rent and Medicare paid Zoll a total of \$15,500.00 to rent a LifeVest for Patient AM.*



152. **Patient LRT**. Below is Zoll's Wear Time Histogram for Patient LRT, a Medicare beneficiary. Zoll's ZPM data reveal this patient wore the LifeVest for 1 full day, and 5 partial days between 4/23/21 and 4/30/21, and then never wore the device again. Despite Patient LRT's almost

complete non-usage of Zoll's LifeVest, Zoll billed Medicare for four months of rent and Medicare paid Zoll a total of \$11,606.77 to rent a LifeVest for Patient LRT.



153. **Patient ARV.** Below is Zoll's Wear Time Histogram for Patient ARV, a Medicare beneficiary. The ZPM data shows that Patient ARV wore the LifeVest fairly consistently for 22 consecutive days: from 5/02/21 to 5/23/2. After that, Patient ARV did not wear the LifeVest again, at all, for approximately four months; at which time, Patient ARV wore the LifeVest again for around 9 days in September 2021; thereafter, Patient ARV never used the LifeVest again. Despite only wearing the LifeVest for approximately 31 days, concentrated in only two months out of a five month stretch of time, Zoll billed Medicare for eight months of rent and Medicare paid Zoll a total of \$21,695.53 to rent a LifeVest for Patient ARV.

154. According to Relator and Zoll's own records, Patient ARV's Wear Time Histogram is also a pattern of use, and non-use, typical of many Zoll patients. Zoll has a scheme to wrongfully generate reorders from physicians.¹⁵ This leads to rentals greater than three months – sometimes much longer, as the eight months billed by Zoll for Patient ARV demonstrates. As with the other

¹⁵ Zoll uses the term reorder to mean obtaining a new prescription from the physician when the initial three-month prescription has expired.

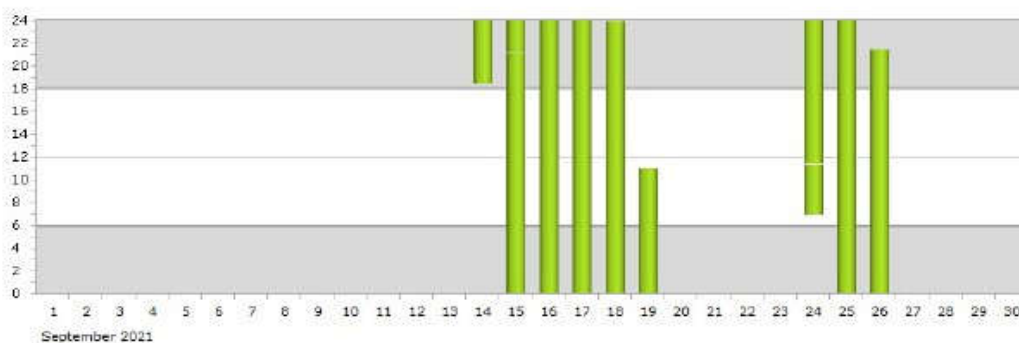
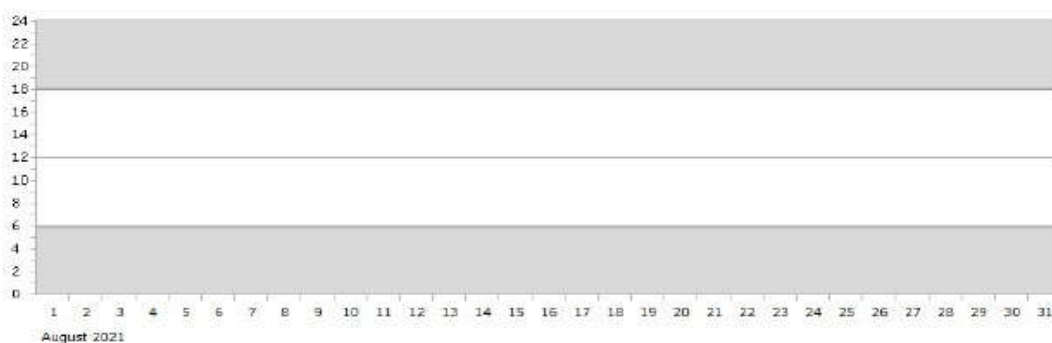
patient examples described above, *Zoll continues to bill Medicare for ongoing monthly rentals when a reorder takes place, even when the patients, like all of the other patient examples, have*



stopped wearing the LifeVest. See Complaint at paras. 183–184, 190–191, and 225–234 for a further discussion of the many fraudulent practices Zoll commits with respect to its physician reordering scheme.



Patient Name: [REDACTED]



2. The Patient Usage, Billing, and Reimbursement Chart

155. In addition to the seven representative patients discussed above, Relator and her counsel used Zoll's ZPM system to prepare a Wear Time Histogram chart for 43 additional Medicare patients (for a total of 50 patients) randomly chosen by Relator as examples of typical patient usage, and non-usage, of Zoll's LifeVest. From these 50 Wear Time Histograms, Relator and her counsel were able to obtain the total number of days that each of the 50 representative patients used Zoll's LifeVest. As noted above, *see* paras. 144-145, Relator and her counsel also examined non-ZPM records maintained by Zoll to determine two other categories of relevant information: 1) the total number of rental months that Zoll billed Medicare for each of the 50

patients, and 2) the total reimbursement, in dollars, that Medicare paid Zoll to rent a LifeVest for each of these 50 patients.

156. Below is a Patient Usage, Billing, and Reimbursement Chart, prepared by Relator and her counsel, that lays out the results of their examination of Zoll's records with respect to each of the 50 selected patients.

Medicare Patient Usage, Billing, and Reimbursement Chart

Patient Name	Total Reimbursement	Total Days of Patient Use	Number of Months Billed by ZOLL
(1) FGP	\$12,761.88	22	6 (180 days)
(2) MCH	\$14,062.52	27	3 (90 days)
(3) EGA	\$10,895.60	40	3 (90 days)
(4) LG	\$8,354.64	9	3 (90 days)
(5) GH	\$11,011.84	60	4 (120 days)
(6) MLR	\$10,725.00	1	4 (120 days)
(7) MLR	\$11,011.74	67	4 (120 days)
(8) JLC	\$11,726.97	66	4 (120 days)
(9) JLN	\$8,185.09	57	3 (90 days)
(10) MMR	\$15,500.00	66	4 (120 days)
(11) SMM	\$10,500.00	4	3 (90 days)
(12) MMM	\$10,633.32	62	3 (90 days)
(13) JMC	\$11,250.00	29	3 (90 days)
(14) AM	\$15,500.00	4	4 (120 days)
(15) PMB	\$4,546.42	19	2 (60 days)
(16) CMO	\$11,465.63	38	5 (150 days)
(17) ARV	\$21,695.53	31	8 (240 days)
(18) ARB	\$8,493.56	20	3 (90 days)
(19) ARM	\$5,456.60	6	2 (60 days)
(20) ARS	\$16,416.25	58	5 (150 days)
(21) APB	\$8,794.35	2	3 (90 days)
(22) CRV	\$3,693.96	1	2 (60 days)
(23) CRR (Deceased)	\$9,921.00	36	3 (90 days)
(24) EPR	\$28,471.00	129	8 (240 days)
(25) JPA	\$15,500.00	76	4 (120 days)
(26) JPT	\$14,070.96	21	5 (150 days)
(27) LRT	\$11,606.77	6	4 (120 days)
(28) LOC	\$5,605.87	6	2 (60 days)
(29) MPM	\$11,625.00	31	3 (90 days)
(30) MRG	\$16,986.52	97	6 (180 days)
(31) MRF	\$23,125.00	97	6 (180 days)
(32) RPS	\$8,190.72	2	3 (90 days)
(33) SRQ	\$9,329.00	39	3 (90 days)
(34) WPA	\$10,499.00	58	3 (90 days)
(35) AST	\$21,765.18	194	9 (270 days)

(36) ATF	\$8,775.32	1	2 (60 days)
(37) CVS	\$7,969.04	1	2 (60 days)
(38) CZ	\$3,875.00	3	1 (30 days)
(39) FS	\$5,851.20	0	2 (60 days)
(40) JTM	\$6,881.01	3	3 (90 days)
(41) JS	\$11,625.00	2	2 (60 days)
(42) MSO	\$11,953.96	3	3 (90 days)
(43) RTR	\$5,683.02	0	2 (60 days)
(44) SVS	\$13,842.61	39	7 (210 days)
(45) AGM	\$4,999.52	12	2 (60 days)
(46) EDV	\$14,443.00	148	6 (180 days)
(47) GD	\$12,722.00	56	4 (120 days)
(48) IF	\$20,925.04	116	5 (150 days)
(49) WGA	\$7,221.86	15	2 (60 days)
(50) JRS	\$8,180.19	5	3 (90 days)
	\$574,324.73		

3. The Patient Usage, Billing, and Reimbursement Chart Shows that Zoll Routinely and Systematically Bills, and Receives Reimbursement for, Ongoing Monthly Rentals When Zoll's Own Records Prove the Patients Have Not Been Using the LifeVest

157. Each time Zoll requests reimbursement from Medicare for an ongoing monthly rental of one of its LifeVests, Medicare requires, *as a condition of payment*, that Zoll verify that the patient *continues to use* and *continues to need* the prescribed LifeVest. Medicare requires this verification from all DME suppliers who rent items on a monthly basis, including Zoll, to ensure that the rented item continues to be *reasonable and necessary* throughout the entire rental period. See Complaint at paras. 130–138, and CMS's "Article A55426: Standard Documentation Requirements for All Claims Submitted to DME MACs." If Zoll cannot show a patient's continued use of its LifeVest, CMS's Article A55426 mandates what Zoll must do: "***Suppliers must discontinue billing Medicare when rental items . . . are no longer being used by the beneficiary.***"

158. Zoll utterly fails to adhere to this mandatory condition of payment. The evidence presented in Relator's Patient Usage, Billing, and Reimbursement Chart confirms what Relator learned from her nearly five years of working at the Company: Zoll routinely and systematically bills, and is reimbursed by the Government, for ongoing monthly rentals of its LifeVests *even when Zoll's own records prove that its patients are not using their LifeVests*. Each one of these bills is a false claim, in violation of the FCA, because Zoll has billed for a LifeVest that was no longer reasonable and necessary due to the patient's complete non-usage of the device.

159. For example, Patient MSO only used a LifeVest for 3 days, yet Zoll billed Medicare for 3 months (90 days); Patient AM only used a LifeVest for 4 days, yet Zoll billed Medicare for 4 months (120 days); Patient WPA only used a LifeVest for 58 days, yet Zoll billed Medicare for 3 months (90 days); Patient MMR only used a LifeVest for 66 days, yet Zoll billed Medicare for 4 months (120 days), and Patient ARV only used a LifeVest for 31 days, yet Zoll billed Medicare for 8 months (240 days).

160. This pattern repeats itself for all of the 50 patients on the Chart: Zoll failed to “discontinue billing” when the LifeVest was “no longer being used by the beneficiary.” *See* CMS’s Article A55426. Instead, Zoll, in blatant disregard of Medicare’s payment rules and in violation of the FCA, billed Medicare for substantially more days than the patient actually used the LifeVest. In fact, for many of the patients on the Chart, Zoll billed Medicare for several times as many days as the patient actually used the LifeVest. *See, e.g.,* Patient FGP, who only used the LifeVest for 22 days and Zoll billed for 6 months (180 days) and Patient AM who only used the LifeVest for 4 days and Zoll billed for 4 months (120 days).

161. In addition, Relator alleges that Zoll’s false billing is *routine* and *systematic* throughout the nationwide Company. By *routine*, Relator means, and alleges, that the patterns of false billing represented by the 50 patient samples in the Patient Usage, Billing, and Reimbursement Chart, occur throughout the Company and apply to the *majority* of Zoll’s patients. Zoll’s false billing is by no means an isolated occurrence. Relator diligently searched through Zoll’s ZPM database for compliant patients that were accurately billed by Zoll: patients who wore their LifeVest continuously, 24 hours a day, for a specific period of time and then Zoll billed a Government Funded Healthcare Program for approximately the same number of days that the patient wore the LifeVest. For example, Relator looked for patients who wore the LifeVest continuously or mostly continuously for close to 30 days and Zoll billed Medicare for just one month or patients who wore the LifeVest continuously or mostly continuously for close to 60 days and Zoll billed Medicare for just two months. Relator located a few such patients, but they were

hard to find and they account for only a small percentage of the patient records in the ZPM database.

162. By *systematic*, Relator means, and alleges, that Zoll's false billing follows a consistent pattern or system. The common patterns of non-usage and false billing are discussed in the previous section of the Complaint under the heading "Zoll's "Wear Time Histogram" Charts: Patient Examples." See Complaint at paras. 141, 146–147, 149, and 154 (describing specific patterns of patient non-usage and false billing). For example, in discussing Patient FPG, Relator explains the most common pattern of non-usage and false billing: Many Zoll patients start out wearing the LifeVest somewhat regularly, but after a couple of weeks their use slows down and they completely stop wearing the LifeVest sometime within, or shortly after, the first month of renting the device. In this common situation, Zoll almost always continues to bill the Government Funded Healthcare Programs for one or more (usually more) ongoing monthly rental periods *after the patient has completely stopped using the LifeVest*.

163. Zoll's systematic false billing patterns result from specific intentional conduct by Zoll. See Complaint at paras. 178–234. Before turning to an explanation of Zoll's specific intentional conduct, however, the next section of the Complaint explains in more detail Zoll's underlying problem with patient non-usage. See Complaint at paras. 164–177.

4. Zoll's Serious Problem with Patients' Non-Usage of its LifeVests

164. Zoll knows it has a serious problem with patients not wearing its LifeVests. For at least the past decade, the ZPM network and its predecessor system have captured patient usage data for all of its patients and Zoll's management and employees all have access to this data. Any review by Zoll of its own patient usage data would necessarily lead to the same conclusion that Relator reached: a majority of patients fail to wear their LifeVests continuously as directed by Zoll and by the patients' physicians. In fact, the ZPM data show that only a small fraction wear their LifeVests continuously for the entire rental period, as they are supposed to do. Instead, the ZPM data show that for at least 50% of the months that Zoll bills the Government, the patients have never worn their Life Vest *at all*, for the entire month that Zoll sought and received reimbursement.

165. Because SCA can happen to high risk patients at any time without warning, when a patient is prescribed a LifeVest, both Zoll and the patients' doctors instruct the patients to wear their LifeVest continuously, 24 hours a day. The only time the WCD should be taken off is when the patient is bathing or showering. This is what it means to use the LifeVest as directed. *See* Complaint at paras. 97–104. Relator does not believe there is any dispute with Zoll over what it means to use the LifeVest as directed. Even Zoll's website states "[i]t is critical that you wear the LifeVest at all times – even while you sleep." *See* Complaint at paragraph 105.

166. To clarify, even though patients are directed by Zoll and their doctors to wear their LifeVests continuously, 24 hours a day, the focus of Relator's Complaint is not on Zoll billing for occasional days in which patients fail to wear their LifeVests for a full 24 hours. On the contrary, Relator's allegations focus on Zoll billing, and the Government paying, for days, weeks and months in a row in which patients have never worn their LifeVests at all: often total non-usage of the device during an entire billing period. The focus is on patients like Patient LRT, who wore the LifeVest for around six days, all within the first month of receiving the LifeVest, and then never wore the LifeVest again. Yet, Zoll billed, and the Government paid, for a second, a third, and (after a reorder) even a fourth month, all in a row, even though the patient never wore the LifeVest during any of those months. *See* Complaint at para. 152.

167. Also, during Relator's almost five years of firsthand observation and experience working at Zoll, as well as the many meetings and conversations she has had over the years with other Zoll employees, Relator has learned that Zoll's patient non-usage problem is well known within the Company. While the general public does not know about Zoll's problem with patients not wearing their LifeVests, those who work for Zoll certainly do.

168. Zoll's problem with patient non-usage arises from the challenges patients face in attempting to wear the LifeVest continuously, 24 hours a day, for weeks and months at a time. Patients struggle to comply for two main reasons. First, the LifeVest is uncomfortable. It is heavy and bulky compared to regular clothing. This creates discomfort and also makes it very difficult for patients to wear the product under their clothing. Also, the LifeVest must be worn directly

against the skin which can lead to rashes, and many patients simply cannot tolerate the restrictive, uncomfortable feeling of the LifeVest against their skin for 24 hours a day. Many patients also complain about it being hot, sweaty, and so binding as to make it difficult for them to move around while wearing the LifeVest.

169. Second, wearing the LifeVest induces anxiety in many patients because of the all-too-understandable fear of receiving an unexpected and painful electric shock. The presence of frequent false alarms greatly exacerbates this anxiety. *See* Complaint at paras. 110–112. The warning alerts and loud voice messaging system that tells the patient to turn off the device to avoid receiving a dangerous electrical shock are a necessary part of the LifeVest design, even if they create false alarms (better to err on the side of inclusiveness rather than miss an SCA event). But, hearing the alarm and knowing that you have only 60 seconds to turn off the device before being kicked in the chest with 3000 volts of electricity can still produce substantial anxiety. As a result, patients complain about the frequency of false alarms and the constant fear they have while wearing the LifeVest.¹⁶

170. For these reasons, many patients stop wearing the LifeVest either right away (within just a few days) or after trying it for a few weeks, in an attempt to get used to it, but then give up. The problem of patient non-usage is also spurred on by the fact that many patients, after a couple of weeks recuperating, start to feel better physically. This gives the patients a false sense of security because despite feeling better they are still at extremely high risk for SCA. Because they feel better and the LifeVest is such a challenge to wear for the reasons just described, after the first few weeks many patients stop wearing the LifeVest completely, and the majority stop well before the initial three-month prescription for the device has run out.

¹⁶ Kestra Medical Technologies makes the only other WCD on the market in the United States, gaining approval just recently, in late 2021. Tellingly, Kestra markets its WCD as being better than Zoll's LifeVest because 1) it is made from lighter materials that, Kestra claims, make it much more comfortable to wear than Zoll's LifeVest, and 2) it incorporates a new technology that, Kestra claims, eliminates many of the false alarms that plague Zoll's LifeVest.

a. The VEST Study

171. Interestingly, a 2018 medical trial funded by Zoll and the National Institutes of Health, known as the Vest Prevention of Early Sudden Death Trial (“VEST”), and published in the New England Journal of Medicine, alludes to Zoll’s problem with patient non-usage.¹⁷ <https://www.nejm.org/doi/full/10.1056/NEJMoa1800781> VEST was designed to test the effectiveness of Zoll’s LifeVest. The trial compared patients prescribed a “wearable cardioverter-defibrillator [the LifeVest] plus guideline-directed medical therapy with guideline-directed medical therapy alone” in patients who had recently suffered an acute myocardial infarction (these are all patients who meet the medical eligibility criteria set out in LCD-L33690). *See* Complaint at paras. 122–123 and paras. 98-100 for a discussion of the medical eligibility criteria and guideline-directed medical therapy.

172. The study reached a somewhat surprising conclusion: “The wearable cardioverter-defibrillator did not lead to a rate of arrhythmic death during the first 90 days – the primary outcome of the trial – that was significantly lower than the rate with guideline-directed medical therapy alone.” In other words, during the 90-day period following a patient’s heart attack, the study found that a prescription for the LifeVest plus the guideline-directed medical therapy did not significantly lower a patient’s rate of death when compared to a control group of similar patients who were only provided with guideline-directed medical therapy.

173. The result seemed to puzzle the authors of the study, at least at first, as the NEJM noted at several points in its article that Zoll’s LifeVest “was effective at converting ventricular tachyarrhythmias, with successful conversion in all 20 participants in the device group who received an appropriate shock.” In other words, during the 90-day study period, the LifeVests detected SCA in 20 patients (approximately 1.3% of the participants in the study group) and the LifeVest successfully revived *all* of these patients with an electric shock from the device’s embedded defibrillator. The authors were surprised to find that even though the LifeVest worked

¹⁷ *See* Jeffrey E. Olgin, M.D., et al. “Wearable Cardioverter-Defibrillator after Myocardial Infarction.” New England Journal of Medicine. 2018 Sept. 27; 379:13:1205-1215

as it was supposed to work, 100% of the time, the death rate for the group that was prescribed LifeVests was not statistically lower than the control group, patients without LifeVests.

174. To account for this discrepancy, the authors of the study suggested the following:

Nonadherence to wearing the device may have reduced the power of the trial to show the effectiveness of this treatment strategy for the prevention of arrhythmic death. The power calculation assumed a device-adherence rate of 70%, a goal that was met or exceeded in the first 2 weeks after randomization but that waned over time. . . . However, in an as-treated analysis, a significantly lower percentage of patients died when they were wearing the wearable cardioverter-defibrillator than when they were not, a finding that remained significant even after the most conservative correction for multiple comparisons. Although this result is subject to bias, it suggests a benefit to wearing the device and implies that low adherence to wearing the device may be a limiting factor in the potential benefit of the wearable cardioverter-defibrillator.

<https://www.nejm.org/doi/full/10.1056/NEJMoa1800781> (emphasis added).

175. To clarify this quote, the authors of the trial surmise that patients' failure to wear their LifeVests throughout the 90-day post-myocardial infarction time period, may have been the reason that the patients who were prescribed a LifeVest did not have a lower death rate than the patients in the control group, who were not prescribed a LifeVest.¹⁸ After all, patients who do not wear their LifeVests are no better protected against SCA than patients who never receive a LifeVest in the first place. The authors support their suggested rationale for the discrepancy by first noting that patient usage of the LifeVest declined substantially after "the first two weeks." See also Complaint at paras. 146–147 (discussing a similar drop off in patient usage of the LifeVest that commonly and consistently shows up in the ZPM database after the first few weeks).

176. The authors then go on to point out that when they compared the overall percentage of patients who died while they were wearing a LifeVest with the overall percentage of patients who died while they were not wearing a LifeVest (what the authors call an "as-treated analysis"),

¹⁸ Another way to look at this is to say that if enough patients in the study group did not consistently wear their LifeVests during the 90-day time period, then the results of the study group (patients who were prescribed a LifeVest) would look, statistically speaking, the same as the control group (patients who were never given a LifeVest). Relator's analysis of the ZPM database appears to confirm this aspect of the VEST study: a majority of patients fail to wear their prescribed LifeVests as directed.

they found a significantly lower death rate among patients when they were actually wearing a LifeVest. This makes sense because the LifeVest, when it is being worn, does appear to be effective: it does detect SCA and it does revive the patient with an electric shock. In other words, *wearing the LifeVest saves lives*.

177. Overall, the VEST study found that patients at high risk for SCA who are *prescribed* a LifeVest do not have a statistically significant lower death rate than patients at high risk for SCA who are *not prescribed* a LifeVest. This is the actual scientific conclusion of the VEST study. But, the authors of the VEST study also suggest that patients who are prescribed a LifeVest – *and actually wear it* – have a lower death rate than patients who do not wear a LifeVest. This is an important (and rather obvious) point which the Complaint discusses further in a later section of the Complaint concerning patient harm. *See* Complaint at paras. 236–239. The results of the VEST study should have, one would hope, motivated Zoll to implement a program to encourage patients to wear their LifeVests as much as possible in order to save as many lives as possible.

5. Zoll’s Intentional Conduct Leads to Its Patterns of False Billing

a. How Zoll handles marketing, billing, and reordering of its LifeVest

178. Zoll markets rentals of its LifeVest through a traditional sales force, much like other medical device manufacturers and pharmaceutical companies. TMs (the position that Relator had while working at Zoll) act as sales representatives for the Company. The TMs call upon cardiologists, and other healthcare providers who work in cardiology practices, hospitals, and outpatient facilities within the TM’s territory in order to sell doctors and their staff on the benefits of renting Zoll’s LifeVest. The TMs work on a salary plus commission basis. TMs are responsible for the initial sale of Zoll’s LifeVests.

179. Once the initial sale has taken place, and a doctor has written a prescription, Zoll fills the prescription by having a Patient Services Representative (“PSR”) fit the LifeVest on the patient and train the patient on how to use the product. PSRs are independent contractors; they

sign a contract with Zoll but they are not employees of Zoll. Once the PSRs have finished with fitting and training the patients, they are not required by Zoll to go back and check on the patients.

180. In fact, there is no one at Zoll who is assigned the responsibility to check on the patients – either by phone or in person – to see how they are doing or if they are actually wearing their LifeVests – after the PSR’s initial fitting and training. No one at Zoll calls or visits the patients once the patient has the LifeVest. Instead, the patients are told that if they have a problem with their LifeVest, they should call the PSR or their doctor.

181. To facilitate the sales, rental, and revenue generating processes, Zoll also employs what it calls a Coordinator of Patient Administration (“CoPA”). CoPA is actually the new name for this full-time employment position at Zoll. Within the past year, the Company changed the name of this position from Sales Support Representative (“SSR”) to CoPA, but the duties and responsibilities stayed the same.

182. CoPAs work with the Zoll sales team, including the TM, assisting and supporting the administrative side of the sales process. The CoPAs also have a crucial role assisting and supporting Zoll’s billing and revenue collection processes. Since Zoll bills insurers directly, including the Government Funded Healthcare Programs, Zoll has an internal billing department. The CoPAs work with Zoll’s internal billing department, as well as with the staff at the patients’ doctor’s offices, to make sure an appropriate prescription, and other relevant paperwork from the patients’ doctors, are on file with Zoll for purposes of billing for the first month, and for all ongoing monthly rentals, of the LifeVest.

183. Perhaps the most crucial role the CoPAs perform for Zoll, however, is the reordering process. As noted above, doctors usually prescribe a LifeVest for a period of three months. An initial prescription is virtually never written for longer than three months. That is because WCDs are intended to be a temporary device and most patients will not need to use a LifeVest for *longer* than three months; it is often less, but rarely longer than three months. The doctors choose three months because that is the maximum amount of time, prior to implantation of an ICD, that it usually takes a doctor to optimize a patient’s arrhythmia medication under

guideline-directed medical therapy. *See* Complaint at paras. 98–100. Of course, a patient may not *need* a LifeVest for all three months or the patient may not *use* the LifeVest for all three months. In either case, Zoll cannot bill the Government for a rental of the LifeVest for the second or third months (the ongoing monthly rental periods) unless the patient continues to need and continues to use the LifeVest during those months.

184. In rare circumstances, such as a severe infection lasting longer than three months or a patient with a particularly difficult arrhythmia problem, a patient may need a LifeVest for an additional one, two or three months. At Zoll, the CoPAs are responsible for handling all aspects of the reordering process, including selling or convincing the doctors on the idea of reordering a LifeVest for their patients. *See also* Complaint at paras. 190–191 and 225–234 (how Zoll’s reordering scheme leads to egregious false billing practices).

b. Zoll has a policy to bill for the length of a prescription, regardless of patient non-usage, which causes it to knowingly bill for LifeVests that are not being used by its patients

185. Government Funded Healthcare Programs will only pay for an ongoing monthly rental of a DME item if the beneficiary “continues to use” the item. The Government defines “continued use” as “the ongoing utilization of . . . a rented item by a beneficiary.” *See* Complaint at paras. 132–137, and CMS’s “Article A55426: Standard Documentation Requirements for All Claims Submitted to DME MACs.” Moreover, the burden of proving a patient’s “continued use” falls on the DME supplier: “[s]uppliers are responsible for monitoring utilization of DMEPOS rental items.” *Id.* Lastly, the Government *mandates* that DME “[s]uppliers must discontinue billing when rental items . . . are no longer being used by the beneficiary.” *Id.*

186. Zoll routinely and systematically violates the Government’s mandate. Through Zoll’s ZPM network, the Company has in place a system that accurately tracks and records each patient’s usage and non-usage of his or her LifeVest. *See* Complaint at paras. 139–140. Thus, Zoll could, if it chose to do so, use its patient monitoring system to verify whether a patient “continues to use” his or her LifeVest and then follow the Government’s mandate to discontinue billing when LifeVests are no longer being used by the patient. But, Zoll chooses not to do this.

187. Instead, Zoll directs the CoPAs, the billing department, and any other administrative staff involved in billing and revenue collection for the Company, that they have no need or obligation to inquire as to whether any patient has been wearing his or her prescribed LifeVest before sending a bill to the Government for an ongoing monthly rental period. As long as there is a valid prescription in place (meaning, the number of months for which the doctor wrote the prescription has not run out), Zoll bills for the month, regardless of the amount of time the ZPM system says the patient has actually used the LifeVest during that month. Thus, despite the fact that the CoPAs and the billing department have access to the ZPM system, Zoll has a policy that no one at Zoll needs to, or should attempt to, look at the ZPM system to verify if a patient has been using his or her LifeVest before billing the Government for an ongoing monthly rental of the device.

188. The reason for Zoll's adoption of this policy is the obvious one. The ZPM system – Zoll's own records – shows devastating levels of patient non-usage. Zoll's own records show that a substantial majority of its patients fail to continuously wear their LifeVests. Those same records show that at least 50% of the time that Zoll submits a bill to the Government for an ongoing monthly rental, the patient has not worn the LifeVest *at all* during the month for which Zoll seeks reimbursement. *See* Complaint at para. 164. Zoll does not verify whether its patients continue to use their LifeVests before billing because, if it did, *and* it followed the Government's mandate to discontinue billing when a patient stops using the device, it would cause a precipitous decline in the Company's revenue.

189. On the other hand, Zoll does make sure there is a valid prescription on file before billing the Government. Most initial prescriptions for the LifeVest are written for three months. So, unless a patient personally returns his or her LifeVest to Zoll before the three months have run (which happens occasionally), Zoll bills for three months – one month at a time – regardless of the amount of time the patient actually wears the LifeVest during any of those months.¹⁹

¹⁹ While Zoll routinely and systematically bills for LifeVests that are not being used by patients, Relator is not aware of Zoll billing for LifeVests that patients have returned to Zoll.

190. Zoll applies the same approach to the billing of reorders. If a CoPA convinces a physician to reorder a LifeVest for an additional month, Zoll bills the Government for an additional month regardless of whether the patient actually wears the LifeVest in the additional month and regardless of whether the patient ever wore the LifeVest during the month before the reorder.²⁰ As soon as the number of months on a patient's prescription or reorder has run out, however, Zoll has a policy and a process in place to pick up the LifeVest from the patient and Zoll stops billing for the device.²¹

191. Zoll's practice of billing for the length of the prescription regardless of patient non-usage explains Zoll's common patterns of false billing: that even though a majority of patients stop wearing their LifeVests well before three months have passed, Zoll almost always continues to bill the Government for one or more (usually more) ongoing monthly rental periods after the patient has completely stopped using the LifeVest. *See* Complaint at paras. 141, 146–147, 149, 154, and 164. This pattern of false billing occurs because Zoll bills for the full length of the prescription *and* any reorders, despite knowing, or recklessly disregarding the truth of the matter, that the patient has stopped using the device.

192. Presumably, Zoll will argue that its conduct is legal because the doctor's prescription alone satisfies the Government's statutory requirement that a rented DME item must be "reasonable and necessary." *See* 42 U.S.C. §§ 1395y(a)(1)(A) and (B). Zoll would be mistaken. When a DME supplier, such as Zoll, submits a claim for reimbursement for an *ongoing* monthly rental of a DME item, there must be information in the medical record to support the fact that the item *continues* to be reasonable and necessary throughout the rental period, *i.e.*, a prescription alone is not enough. Further, Zoll must submit a new and separate CMS-1500 claim form for each

²⁰ Note, as discussed below at paragraphs 224–233, when a CoPA reaches out to a doctor to try and get a reorder (a transaction for which Zoll pays the CoPA a commission), Zoll does not require that the CoPA tell the doctor about the patient's non-usage of his or her LifeVest. This makes it much easier for the CoPAs to get reorders from physicians.

²¹ Relator notes that Zoll's adherence to the CMS requirement that a prescription be on file before billing for the LifeVest shows that, when Zoll wants to, it can follow at least one of Medicare's conditions of payment. *See* LCD-L33690 (DME suppliers must have a valid prescription on file before seeking reimbursement from Medicare for the rental of a LifeVest).

month that it seeks reimbursement, throughout the rental period, and each one of those separate claim forms must certify that the LifeVest is reasonable and necessary for that particular month. For example, one of the most common situations at Zoll is where a doctor writes a prescription for three months and the patient stops wearing his or her LifeVest sometime in the first month and then never wears it again. In that quite typical situation, virtually every time, Zoll bills for all three months. It submits a CMS-1500 claim form seeking reimbursement not just for the first month, but also for the entire second month, and the entire third month. For each one of those subsequent claim forms, Zoll certifies that the LifeVest is reasonable and necessary even though Zoll knows the patient did not wear the device at all. Put simply, that is not reasonable and the certification and the claim form are false.

193. To facilitate the enforcement of the requirement that a rented DME item must be “reasonable and necessary” throughout the rental period, Medicare has adopted two conditions of payment for the reimbursement of an ongoing monthly rental of a DME item: that the beneficiary continues to need *and continues to use* the rented DME item. *See* LCD-L33690 and CMS’s “Article A55426; Standard Documentation Requirements for All Claims Submitted to DME MACs; and Complaint at paras. 130–137.

194. With this in mind, Zoll may also argue, it would seem, that the prescription shows that the patient *needs* the LifeVest, not just for the first month of the prescription, but for the full length of the prescription, and that this need justifies Zoll continuing to bill for the LifeVest throughout the length of the prescription. But, such an argument fails to take account of the fact that a patient must continue to need *and continue to use* the rented DME item before the Government will pay for it.

195. Relator understands that many of Zoll’s patients continue to need the LifeVest, even if they have stopped using it. As Relator has previously stated, patients who meet the eligibility criteria for a WCD, as laid out in LCD-L33690, Part I, are extremely ill. They are at high risk for succumbing to SCA and arguably need to wear a LifeVest to survive. But, when patients who need a LifeVest stop wearing it for consecutive days, weeks, and months in a row, it is simply not

reasonable for the Government to continue to pay for the device. The statutory standard that Zoll must adhere to is whether the rental of the LifeVest is “*reasonable and necessary*.” Continuing to pay for a LifeVest that a patient has completely stopped using for long periods of time is not reasonable. It is not even rational.

196. This is exactly why CMS has implemented its rule that the Government will only pay for ongoing monthly rentals if the patient continues to use the DME item. *Not every patient who needs a DME rental item will continue to use it*. When that happens, it is not “reasonable” for the Government to continue to pay for it. That is why even when a patient still needs a particular DME item, Medicare mandates that DME “[s]uppliers *must* discontinue billing Medicare when rental items . . . are no longer being used by the beneficiary.” See CMS’s “Article A55426; Standard Documentation Requirements for All Claims Submitted to DME MACs” (emphasis added).

197. Take, for example, a motorized wheelchair or oxygen equipment for use at home: two common DME items that Medicare pays for on a rental basis. A patient may have a valid prescription to rent either product and the patient, due to a debilitating physical condition, may meet the medical criteria for needing either or both DME items. But, if the patient does not use them or stops using them altogether because, for example, the patient does not like using a motorized wheelchair or the patient does not feel comfortable using the oxygen equipment, it would not be reasonable for the Government to continue to pay for ongoing monthly rentals of either product, even if the patient still legitimately needs the product. In both instances, as with the LifeVest, Medicare requires that the DME supplier “must discontinue billing Medicare” when the rental items “are no longer being used by the beneficiary,” even if the patient still arguably needs the product.

c. Zoll’s “Don’t Ask, Don’t Tell” policy leads to more false billing

198. Zoll has also adopted what the Relator refers to as a “Don’t Ask, Don’t Tell” policy with respect to patients’ non-usage of its LifeVests. The short version of the policy is the following: don’t ask non-compliant patients to wear their LifeVests and don’t tell the doctors about their

patients' non-usage of their LifeVests. Below, the Complaint explains the policy and how it contributes to, and exacerbates, Zoll's pattern and practice of false billing for non-compliant patients.

(i) Zoll does not ask non-compliant patients to wear their LifeVests

199. As noted in several places in the Complaint, Zoll's own records show that a substantial majority of its patients fail to continuously wear their LifeVests. Given Zoll's big problem with patient non-usage, one would think that Zoll would have a policy and procedure in place to reach out to patients who are not using their LifeVests, to ask and encourage these patients to wear their LifeVests.

200. Adopting such an outreach program would serve two important purposes. One, for those patients who listened to Zoll's encouragement and started wearing their LifeVests on a regular basis, it would allow Zoll to legally bill the Government Funded Healthcare Programs for ongoing monthly rental periods. This is obviously in Zoll's best interest because it would increase the Company's legitimate revenue.

201. Two, it would save lives. The Complaint explains how patients who meet the medical eligibility criteria for the LifeVest have an extremely high risk for SCA. *See* Complaint at paras. 83–89, 97–103, and 113–114. Zoll knows that for the LifeVest to be effective, its patients must actually wear their LifeVests. When patients wear their LifeVests, it saves lives. To put it bluntly and accurately, when Zoll's ZPM system reveals to Zoll that a patient is not wearing his or her LifeVest, Zoll knows that the patient is at a greater risk of dying than if he or she were wearing their LifeVest. Reaching out to these many thousands of patients across the country to encourage them to wear their LifeVests would unquestionably save lives. The VEST study, discussed above, suggests the same thing: patients at high risk for SCA who are wearing their prescribed LifeVests have a lower death rate than high risk patients who are not wearing their LifeVests. *See* Complaint at paras. 174–177; NEJM, 2018 Sept. 27 at 1210 (the VEST trial “suggests a benefit to wearing the [LifeVest] and implies that low adherence to wearing the device may be a limiting factor in the potential benefit of the wearable cardioverter-defibrillator.”)

202. Knowing how important wearing the LifeVest is to patients, one would think Zoll would have an aggressive outreach program designed to encourage non-compliant patients to wear their LifeVests. But, despite the obvious benefits, including the fact that it would save lives, Relator is not aware of any such policy or procedure at Zoll during her almost five years of working at the Company. Despite having a system in place that lets Zoll know exactly which patients are not wearing their LifeVests, Relator is not aware of Zoll using that information to reach out to non-compliant patients, by phone, electronically, or in person, to ask or encourage these patients to wear their LifeVests or to even check up on the patients to see how they are doing.

203. Based upon her firsthand experience at Zoll, and her conversations over the years with many Zoll employees, doctors, staff at doctor's offices, and patients themselves, Relator alleges the reason Zoll does not reach out to patients who have stopped using their LifeVests is because the Company is concerned that many non-compliant patients would return their LifeVests to Zoll rather than start wearing them.²² Because returning the LifeVests would reduce the revenue Zoll receives *from its improper billing for non-compliant patients*, Zoll has not implemented a policy and procedure to reach out to non-compliant patients to encourage them to wear their LifeVests.

204. Note, if Zoll had a policy to discontinue billing when patients stopped using their LifeVests, as the Government mandates, then having non-compliant patients return their LifeVests would not reduce the Company's revenue. That is because Zoll would not have been able to bill for non-compliant patients anyway, so it would not hurt Zoll financially if the patients returned their LifeVests. It would actually benefit Zoll because the Company would have its LifeVests back and available to rent to other patients. But, for Zoll, it is more profitable to say nothing to the patients, which allows the Company to keep making money billing non-compliant patients, than it is to reach out to the non-compliant patients and risk having them return their LifeVests.

²² Some patients would undoubtedly return their LifeVests if contacted by Zoll. Relator encountered quite a few non-compliant patients who simply wanted to return their LifeVests.

205. In summary, Zoll makes millions of dollars by falsely billing the Government for LifeVests that are not being worn at all. *See* Complaint at paras. 155–163. As long as the prescription has not expired and as long as the patient has not returned the LifeVest, Zoll continues to bill for ongoing monthly rentals of its LifeVests, regardless of patient non-usage. So, when a non-compliant patient returns a LifeVest before the prescription has run, it causes Zoll to “lose” money on its false billing scheme. Since reaching out to non-compliant patients to ask them to wear their LifeVests would cause some of them to return their LifeVests, Zoll has not implemented an outreach program to encourage non-compliant patients to wear their LifeVests.

(ii) Zoll does not tell doctors about their patients’ non-usage

206. Similarly, despite having a monitoring system in place that lets Zoll know exactly which patients are not wearing their LifeVests, Zoll has no policy or procedure in place to reach out and tell prescribing doctors about their patients’ non-usage, even when patients are not wearing their LifeVests for days, weeks and months at a time.

207. Zoll does not tell the doctors about their patients’ non-usage for the same reason it does not reach out to non-compliant patients to urge them to wear their devices: telling the doctors would lead to many non-compliant patients returning their LifeVests to Zoll before the prescriptions had run out and this would reduce Zoll’s revenue. Zoll would “lose” money because the doctors would intervene; they would take steps to treat their patients’ underlying heart condition and speed their transition to an ICD. This eliminates or shortens the patient’s need for a LifeVest causing the patient to return the LifeVest to Zoll before the prescription has run out. This returning of the LifeVest hurts Zoll’s “profits” because, as noted above, when a non-compliant patient returns an unused LifeVest before the prescription has run out it causes Zoll to “lose” money from its scheme to bill for non-compliant patients. This is why Zoll has not implemented a policy and procedure to tell doctors that their patients have stopped wearing their LifeVests.

208. Relator knows from firsthand experience that when doctors are alerted to the fact that one of their patients has stopped using his or her LifeVest, the doctors take immediate steps to help such patients. The doctors do so because they know that their patients who meet the medical

eligibility criteria for wearing a LifeVest have a high risk of developing SCA and if these high-risk patients are not wearing their LifeVest, they will likely die if SCA strikes them.

209. The doctors can take steps to help their non-compliant patients. For one thing, doctors can accelerate the patient's transition to an ICD which would eliminate the patient's need for a LifeVest. A doctor learning of a patient's non-usage will usually meet with the patient as soon as possible to see if the patient has already stabilized enough to receive an ICD. The doctor may order tests right away to help with this determination. Also, doctors will usually order an immediate consultation with an electrophysiologist ("EP") for evaluation and testing of the patient's readiness and fitness to have an ICD implanted (an EP is a cardiologist who specializes in testing and treating cardiac arrhythmias). Once the patient receives an ICD, the patient will no longer need a LifeVest and will return it to Zoll.

210. Also, when alerted to a patient's non-usage of his or her LifeVest, the doctor will work quickly to better stabilize the patient's underlying arrhythmia problem. For example, doctors will order additional diagnostic tests to be done as soon as possible (such as an echocardiogram or a multigated acquisition scan). These tests analyze the heart's ejection fraction and allow the doctor to better treat any underlying problem. If the ejection fraction has improved (something which often happens with patients over time and with the use of medication), the patient can get an ICD or the doctor can decide the patient no longer needs a LifeVest: either way, the doctor will have the patient return the LifeVest to Zoll.

211. In addition, the doctor will also make an appointment to see the patient right away to speed up the optimization of the patient's arrhythmia medication under guideline-directed medical therapy. This is important because drug optimization often reduces a patient's SCA risk low enough that the patient will no longer need a LifeVest. Also, just as importantly, the quicker that drug optimization can be accomplished, the faster a patient can have an ICD implanted. Again, this means the patient will no longer need the LifeVest and the doctor will have the patient return the LifeVest to Zoll.

212. Thus, overall, doctors have several medical options available to them to help treat non-compliant patients: treatments which 1) will improve their patients' medical condition sufficiently enough that the patient no longer needs a LifeVest or 2) will allow the patient to more quickly receive an ICD which eliminates the need for a LifeVest. Neither of these options allows Zoll to continue billing for its non-compliant patients, so Zoll does not reach out and tell the doctors about their patients' non-usage of their LifeVests.

213. Remember, as Defendant Asahi Kasei states on its website: "[t]he LifeVest allows a physician time to assess the patient's long-term arrhythmic risk and make appropriate plans." *See* Complaint at para. 114. This is true – but only as long as the patient is wearing the LifeVest as directed. To paraphrase the Defendant, when the doctor learns that a patient is not wearing his or her LifeVest as directed, the doctor has to speed up the process of assessing the patient's "long-term arrhythmic risk" and accelerate the timetable for making "appropriate plans," especially the implantation of an ICD, as soon as possible to reduce the chance of a non-compliant patient dying during the transition period. But, by not telling the doctors about their patients' non-usage, Zoll denies the doctors this opportunity to speed up the process of protecting their patients' lives.

214. In summary, as long as the prescription has not run and as long as the patient has not returned his or her LifeVest, Zoll continues to bill for ongoing monthly rentals of its LifeVests, regardless of patient non-usage. If Zoll were to reach out and tell the doctors about their patients' failure to wear their LifeVests, doctors have several treatment options they could use to help their non-compliant patients. Most importantly, the doctors could take positive steps to more quickly stabilize their patients and to implant an ICD: actions that would eliminate the need for a LifeVest and cause the patient to return the device to Zoll. Since reaching out to the doctors of non-compliant patients to tell them about their patients' non-usage would cause some LifeVests to be returned before the end of the prescription, reducing the amount of money Zoll can make from its false billing scheme, Zoll has not implemented a policy of reaching out to the doctors to tell them about their patients' non-usage of the devices.

215. Zoll's failure to tell the doctors about their patients' non-usage leads to substantial patient harm. If doctors are alerted to their patients' non-usage of their LifeVests, the doctors will take action to protect their patients with other treatment options until the patients can receive an ICD. The opposite is also true. Zoll's failure to reach out and tell the doctors deprives the patients of these other treatment options and leaves these high-risk patients without protection from death by SCA. *See* Complaint at paras. 235–241 for a further discussion of patient harm.

216. With respect to the “Don’t Tell” policy, presumably, Zoll will argue that it has no legal obligation to tell the doctors about their patients' non-usage of their LifeVests and, in any event, the doctors could sign up for Zoll's ZPM monitoring system themselves and use it to check on their patients. Relator will address each of these points, respectively.

217. First, under the FCA, Zoll is correct it does not have a legal obligation to tell the doctors about their patients' non-usage. Relator believes Zoll has an ethical and moral obligation to tell the patients' doctors so the doctors can help their patients mitigate the harm that arises from failing to wear their LifeVests. But, failure to tell the doctors does not violate a legal obligation under the FCA. But, this misses Relator's point. When a patient stops wearing his or her LifeVest, Zoll has one specific and very important legal obligation under the FCA: it *must* discontinue billing the Government Funded Healthcare Programs. Zoll cannot continue to bill for a LifeVest that a beneficiary does not continue to use. It is not reasonable; it is not even rational, for Zoll to bill the Government, and for the Government to pay, for DME rental items that are not being used at all, often for weeks and months in a row. Zoll routinely and systematically violates this legal obligation and the FCA by billing for patients who have stopped using their LifeVests.

218. Relator's point in raising the issue of the “Don’t Tell” policy is that Zoll fails to reach out and tell the doctors about their patients' non-usage so that Zoll can *continue* to bill for non-compliant patients even after the patients have stopped wearing their LifeVests. Put another way, making money from the billing of non-compliant patients, in violation of the FCA, has incentivized Zoll to adopt the “Don’t Tell” policy. If Zoll told the doctors, the doctors would intervene and cause the patients to return their LifeVests before the prescription or reorders ran

out. The “Don’t Tell” policy thus enables Zoll to continue to make millions of dollars falsely billing the Government in violation of the FCA.

219. Relator’s other point in raising the issue of Zoll’s “Don’t Tell” policy is that it leads to substantial patient harm. The patient harm arises because failing to tell the doctors about their patients’ non-usage deprives these patients of the medical care that the doctors would provide if they were aware of their patients’ non-usage. The causal relationship is straightforward: Zoll’s desire to make even more money from billing for non-compliant patients, in violation of the FCA, is the reason for the “Don’t Tell” policy and that policy leads to substantial patient harm. *See* Complaint at paras. 235–241 for a further discussion of this patient harm.

220. Second, as Zoll may point out, Zoll does allow doctors to have access to its ZPM patient monitoring system. Doctors can enroll in the network, free of charge, which allows the doctors to log into the application from their office computers and see the data the ZPM system has collected on their patients. The Company asks its TMs and other employees who have contact with prescribing doctors to encourage them to join the ZPM network. This is a good thing and Relator herself has attempted many times to get the doctors she called upon when she worked for Zoll to join the ZPM network.

221. In practice, however, the reality is that only a very small percentage of prescribing doctors use the ZPM system. Doctors have very busy schedules and focus their medical practices on seeing and treating patients with appointments who come to their office, clinic, or other outpatient facility. The doctors claim they do not have the time or the staff to use the ZPM system. Zoll knows this too. Zoll can tell which doctors have joined ZPM, which ones have logged onto the system and for how long, and which patient data the doctors have examined. So, Zoll knows that few doctors have signed up for the ZPM system and that even fewer doctors use the ZPM system to check on their patients.

222. Relator also alleges based on firsthand knowledge and her many years of working at Zoll that doctors who prescribe LifeVests for their patients are under the mistaken belief that Zoll already actively monitors their patients for compliance and that Zoll will notify them if their

patients stop using their LifeVests. The prescribing physicians consider – correctly – that it is Zoll's responsibility to monitor whether the patients are wearing their LifeVests. The doctors believe that if their patients are non-compliant, Zoll will let them know, and will take back the device from their patients. That makes complete sense from the doctors' perspective because no rational DME supplier would allow a patient to keep the supplier's product when the patient is not using it since the supplier can no longer make any money from the device. The doctors, like most people, think that a supplier cannot bill for a product the patient is not using so the DME supplier would go pick it up if the patient is not using it.

223. But Zoll does not do that. As alleged throughout the Complaint, Zoll knows when patients are non-compliant, does not ask the non-compliant patients to wear their LifeVests, and does not reach out and tell the doctors about their patients' non-usage of their devices, but continues to bill for non-compliant patients anyway. Zoll's failure to specifically notify the prescribing physicians that their patients are non-compliant misleads the physicians into believing that their patients are compliant and well protected from SCA when so many of their patients are not.

224. Finally, it is important to note that whether or not the prescribing doctors use the ZPM system to monitor their patients is irrelevant to Zoll's submission of false bills in violation of the FCA. Zoll, the DME supplier, and only Zoll, is responsible for monitoring utilization of its LifeVests and to discontinue its billing of the Government when its LifeVests are no longer being used by the patient. *See* Complaint at paras. 135–137; and CMS's "Article A55426: Standard Documentation Requirements for All Claims Submitted to DME MACs." Zoll is the one who submits the false bills to the Government erroneously certifying that the unworn LifeVests are reasonable and necessary. Whether a few doctors are also using the ZPM system to check the status of their patients does not change, at all, Zoll's responsibility to not bill the Government when patients are not wearing their LifeVests.

d. Zoll uses its “Don’t Ask, Don’t Tell” policy to wrongfully generate reorders of its LifeVests

225. In a particularly brazen violation of the Government’s rules and regulations, Zoll also uses its “Don’t Ask, Don’t Tell” policy to wrongfully generate reorders of its LifeVests. As described above, *see* Complaint at paras. 98–99 and 183–184, an initial prescription for a LifeVest is almost always written for three months. The medical standard is a three-month prescription because the vast majority of patients will not need to use a LifeVest for longer than three months. From a medical perspective, three months makes sense because it is the maximum amount of time that it usually takes to stabilize a patient prior to implantation of an ICD, the ultimate therapeutic goal for patients at high risk for SCA.

226. In rare circumstances, such as a severe infection lasting longer than three months or a patient with a particularly difficult arrhythmia problem, a patient may need a LifeVest for an additional one, two or three months. In that situation, the doctor will write a prescription for an extra month (usually the doctor only writes a prescription for one additional month at a time). Zoll uses the term reorder to refer to the doctor’s prescription for an additional month of the LifeVest, either after the initial three-month prescription has run out or after a reorder has run out.

227. At Zoll, the CoPAs are responsible for handling all aspects of the reordering process, including selling or convincing the doctors on the idea of reordering a LifeVest for their patients. Zoll treats reorders as a colossal money-making opportunity; it has been a huge success. Throughout the Company, CoPAs are known as one of the key drivers of Zoll’s entire revenue stream. That is because reorders have become extremely common at Zoll and because they give Zoll an additional one or more (sometimes many more) months of revenue at little or no additional cost to the Company.

228. Zoll promotes and encourages its CoPAs to obtain as many reorders as they can by treating reorders like traditional sales. It does this by paying CoPAs a commission on their reorders, in two different ways. First, it pays the CoPAs a generous salary and then sets a sales goal for reorders that is quite high. This achieves its intended effect of incentivizing the CoPAs to aggressively solicit reorders from prescribing physicians so they can meet their goal and keep their

lucrative employment. Second, Zoll pays a commission per reorder for those industrious CoPAs who can generate reorders above and beyond their sales goal.

229. Zoll then makes it much easier for the CoPAs to get reorders by applying its “Don’t Ask, Don’t Tell” policy to the handling of reorders by the CoPAs. First, Zoll has no requirement that the CoPAs speak to the patients when attempting to obtain a reorder, let alone actually ask the patients if they want a reorder. The CoPAs only need to call the patient’s doctor to get a reorder. Not surprisingly, given that the CoPAs have a high sales goal to meet and the incentives of a commission structure, the CoPAs rarely call the patients, simply because they do not have to do so. As noted in many places throughout the Complaint, most patients are non-compliant so asking them if they would like to keep an unused LifeVest for even longer would not help the CoPAs generate more reorders.

230. Second, *Zoll has no requirement that the CoPAs tell the doctors about their patients’ non-usage of their LifeVests when seeking a reorder from the doctor.* It is astonishing that Zoll has no such requirement. Continued patient usage of their LifeVest is crucial to the decision whether to reorder a LifeVest and critical to protecting the patient from death by SCA. But, that is the policy. If the doctor asks the CoPA about his or her patient’s usage, Zoll has no prohibition against giving out this information and the CoPA can tell the truth. But, in practice, few doctors ask. Most doctors are very busy and, anyway, the CoPA is often speaking with someone in the doctor’s staff who is in charge of prescriptions and the staff are also busy and usually they do not ask about patient usage either. Plus, as noted above, most doctors believe that Zoll is monitoring their patients’ usage and that Zoll *would inform them* of a problem with patient non-compliance if there was one.

231. Given that the CoPAs have a high sales goal to meet and the incentives of a commission structure and Zoll does not require them to do so, *most CoPAs do not tell the doctors about their patients’ non-usage of their LifeVests when asking the doctor or the doctor’s office for a reorder.* If asked by the doctor about it, Relator believes that the CoPAs will generally tell the truth about the patients’ usage and non-usage. The reason that CoPAs do not volunteer the

information regarding the patient's non-usage is the obvious one: the CoPAs want to sell reorders. CoPAs know from experience, especially from telling the doctors who do ask, that telling a doctor that a patient is non-compliant eliminates any chance of obtaining a reorder from that doctor. When told about their patients' non-compliance, the doctors not only refuse the reorder they also take action to help their patients reduce their risk of SCA to prevent patient harm. *See Complaint at paras. 208–214 and 237–238.*

232. Overall, the sale of reorders at Zoll has been a huge success. A large percentage of all Zoll patients receive a reorder for at least one month. In the Chart prepared by Relator and her counsel that lays out the usage, billing, and reimbursement for 50 sample patients, 21 of the patients (40%) received a reorder. *See Complaint at para. 156.* Relator alleges that the 40% figure is comparable to reorder percentages across the country.

233. An examination of individual sample patients shows the egregious nature of the false billing that occurs with Zoll's reorders. For example, according to Zoll's own records, Patient AM wore the LifeVest for only a few hours on four separate days and then never wore the device again. Despite Patient AM's sparse use of the LifeVest, Zoll billed Medicare for *four months* of rent and Medicare paid Zoll a total of \$15,500.00 to rent a LifeVest for Patient AM. *See Complaint at para. 151.* Sometime before the end of the third month, a CoPA obtained a reorder from the doctor for an additional month despite the fact that the patient had not worn the LifeVest at all for almost the entire three months of the initial prescription. Then, Zoll proceeded to bill, and receive reimbursement for, an entire additional fourth month of rent even though the patient again never wore the LifeVest at all.

234. Similarly, according to Zoll's own records, Patient FGP used a LifeVest for 19 full days and 3 partial days, all within the first month of the prescription, and never wore the device again. Thereafter, however, Zoll billed Medicare for *six months* of rent and Medicare paid Zoll a total of \$12,761.88 to rent a LifeVest for Patient FGP. *See Complaint at paras. 142–144.* Sometime before the end of the third month, a CoPA obtained a reorder from the doctor for an additional month despite the fact that the patient had not worn the LifeVest at all for the last two months.

After that, the CoPA obtained one or two more reorders for a total of three additional months despite no additional use of the LifeVest. Overall, despite no use at all by Patient FGP for five consecutive months, Zoll billed, and received reimbursement, for the entire original three-month prescription, and for an entire additional fourth, fifth, and sixth months of rent from reorders even though the patient never again wore the LifeVest after the first month.

6. Zoll's False Billing Scheme Leads to Serious Patient Harm

235. The Zoll LifeVest is a wearable garment that contains an external defibrillator. Patients who meet the medical eligibility criteria for a LifeVest bear an extremely high risk for SCA. Zoll's LifeVest is worn as a safeguard against dying from SCA while the patient awaits implantation of an ICD or another long-term preventative treatment, such as medication optimization under guideline-directed medical therapy. The LifeVest, while being worn by the patient, continuously monitors the patient's heart for signs of SCA and treats the patient with an external shock if the patient develops SCA. Since SCA can occur at any time, without warning, the LifeVest should be worn continuously, as much as possible, for it to be truly effective. *See Complaint at paras. 97–105.*

236. By all accounts, when a patient wears a LifeVest, the LifeVest performs well. Wearing the LifeVest saves lives. Zoll's problem with its LifeVest – a problem which it knows well – is that most of its patients are non-compliant: they stop wearing their LifeVests, usually after a few weeks, and many never put on the LifeVest again. These very ill, high-risk and non-compliant patients are at risk of dying from SCA since they are not wearing their LifeVests.

237. When patients stop wearing their LifeVests, doctors have several medical options available to help reduce these non-compliant patients' risk of dying from SCA. *See Complaint at paras. 208–214.* First and foremost, the doctor will immediately evaluate the patient for implantation of an ICD, the gold standard of preventative treatment for patients at high risk for SCA. The doctor takes this step because, in the time period since the patient was first prescribed a LifeVest, many times the patient's condition has improved enough to have an ICD immediately implanted. The doctor will also immediately speed up the patient's drug optimization procedure.

This may improve the patients' medical condition sufficiently enough that the patient no longer needs a LifeVest; it may also accelerate the patient's transition to an ICD.

238. Zoll's conduct leads to patient harm, among other things, because, despite having a monitoring system in place that lets Zoll know exactly which patients are not wearing their LifeVests, Zoll does not reach out and tell the prescribing doctors when their patients stop wearing their LifeVests. Zoll's failure to tell the doctors deprives the patients of the treatment options available to non-compliant patients described above. It also harms these high-risk patients because it leaves them without any protection from death by SCA. Zoll does not tell the doctors about their patients' non-usage of their LifeVests so that it can continue to bill for its non-compliant patients without any interference from the doctor, at least until the prescription has run out.

239. There is obviously no way to quantify precisely how many patients have been harmed or have died as a result of Zoll's failure to alert the doctors to the non-compliance of their patients. The VEST study, however, provides an idea of the scope of the harm. *See* Complaint at paras. 171–177. In that 90-day trial, the test group, which had been prescribed LifeVests, consisted of approximately 1,500 patients. From this group, 20 patients (approximately 1.3%), received an appropriate shock, meaning the LifeVest accurately detected SCA within the 90 days of the trial and the device successfully revived the patient. NEJM, 2018 Sept. 27 at 1205; <https://www.nejm.org/doi/full/10.1056/NEJMoa1800781>. This suggests that the rate of developing SCA in the VEST trial among compliant patients, over the 90-day period of the trial, was approximately 1.3%. Applying even just a fraction of this 1.3% SCA rate to the many thousands of high-risk non-compliant patients that Zoll knows have not been using their LifeVests over the last several years suggests a distressingly high number of potential deaths. It is certainly greater than zero.

240. The other important point to note here is that the patient harm is directly tied to Zoll's willingness to violate the FCA. If Zoll had routinely and systematically followed the Government's mandate and discontinued billing for the LifeVest when patients stopped using the device, Zoll would not have submitted false bills in violation of the FCA. In that situation, Zoll

would have been incentivized to alert the doctors to their patients' non-usage. That is because Zoll would have wanted to tell the doctors about their patients' non-compliance so they could get the LifeVest back from the patient. Zoll would be losing money when a LifeVest went unused but stayed in the possession of the patient. Zoll would want its device back so it could rent it to another patient.

241. Instead, Zoll routinely and systematically bills the Government for patients who are not using their LifeVests in violation of the FCA. The false billing scheme has incentivized Zoll to keep quiet and not tell the doctors about their patients' non-usage so the Company can keep billing for its non-compliant patients. This has, in turn, led to the substantial patient harm described above.

VI. CLAIMS FOR RELIEF

COUNT ONE

(Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(A))

242. Relator repeats and realleges the preceding paragraphs as if fully set forth herein.

243. This is a civil action brought by Relator, on behalf of the United States of America, against Defendants pursuant to the False Claims Act, 31 U.S.C. § 3730(b)(1).

244. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims for payment or approval under the Government Funded Healthcare Programs to officers, employees, or agents of the United States Government, in violation of 31 U.S.C. § 3729(a)(1)(A).

245. For the reasons alleged herein, the claims were false or fraudulent because they were presented, or caused to be presented, *inter alia*, for Zoll LifeVests that were not reasonable and necessary and Zoll did not comply with all applicable laws, regulations, and program instructions for payment.

246. The Government, unaware of the falsity of the claims and/or statements made or caused to be made by Defendants, and in reliance on the accuracy of these claims and/or

statements, including certifications, paid, and continue to pay, for these invalid claims for products rented to recipients of the Government Funded Healthcare Programs. If the Government had known about the violations, the Government would not have paid for the claims.

247. As a result of Defendants' actions as set forth above, the Government has been, and continues to be, severely damaged.

COUNT TWO
(Federal False Claims Act, 31 U.S.C. § 3729(a)(1)(B))

248. Relator repeats and realleges the preceding paragraphs as if fully set forth herein.

249. This is a civil action brought by Relator, on behalf of the United States of America, against Defendants pursuant to the False Claims Act, 31 U.S.C. § 3730(b)(1).

250. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false or fraudulent records and/or statements to get false or fraudulent claims paid under the Government Funded Healthcare Programs in violation of 31 U.S.C. § 3729(a)(1)(B).

251. For the reasons alleged herein, Defendants made or caused to be made numerous false records and statements, including false statements in claim forms that the claims met the Government Funded Healthcare Programs' requirements that the claims be for reasonable and necessary products and that Zoll complies with all applicable laws, regulations, and program instructions for payment. As a result of these false records and statements, false claims for payment were submitted to, and paid for by, the relevant Government Funded Healthcare Programs.

252. The Government, unaware of the falsity of the claims and/or statements made or caused to be made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for certain of Defendants' products rented to recipients of the Government Funded Healthcare Programs. If the Government had known about the violations, the Government would not have paid for the claims.

253. As a result of Defendants' actions as set forth above, the Government has been, and continues to be, severely damaged.

COUNT THREE
(California False Claims Act, Cal. Gov't Code § 12650, *et seq.*)

254. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

255. Based on the foregoing allegations, Defendants are liable under Cal. Gov't Code § 12650, *et seq.*

COUNT FOUR
(California Insurance Frauds Prevention Act, Cal. Ins. Code § 1871.7(a))

256. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

257. Cal. Ins. Code § 1871.7(a) provides that "it is unlawful to knowingly employ runners, cappers, steerers, or other persons . . . to procure clients or patients to perform or obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured individual or his or her insurer."

258. Through the actions described above, Defendants violated Cal. Ins. Code § 1871.7(a), by knowingly employing runners, cappers, steerers, or other persons to procure clients or patients to perform or obtain services or benefits under a contract of insurance, or that will be (and were) the basis for a claim against an insured individual or his or her insurer.

COUNT FIVE
(Violation of Cal. Ins. Code § 1871.7(b) and Cal. Penal Code § 550(a))

259. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

260. Cal. Ins. Code § 1871.7(b) provides that "[e]very person who violates any provision of this section or Section 549, 550, or 551 of the Penal Code shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than five thousand

dollars (\$5,000) nor more than ten thousand dollars (\$10,000), plus an assessment of not more than three times the amount of each claim for compensation.”

261. Cal. Penal Code § 550(a) provides that “[i]t is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following ... (1) Knowingly present or cause to be presented any false or fraudulent claim for the payment of a loss or injury, including payment of a loss or injury under a contract of insurance [and] (5) Knowingly prepare, make, or subscribe any writing, with the intent to present or use it, or to allow it to be presented, in support of any false or fraudulent claim.”

262. Through the actions described above, Defendants violated Cal. Penal Code § 550(a), and in turn, Cal. Ins. Code § 1871.7(b).

COUNT SIX
(Colorado Medicaid False Claims Act, Col. Rev. Stat. §§ 25.5-4-303.5 to 25.5-4-310)

263. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

264. Based on the foregoing allegations, Defendants are liable under Col. Rev. Stat. § 25.5-4-303.5 *et seq.*

COUNT SEVEN
(Connecticut False Claims Act, Conn. Gen. Stat. § 4-274 *et seq.*)

265. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

266. Based on the foregoing allegations, Defendants are liable under Conn. Gen. Stat. § 4-274 *et seq.*

COUNT EIGHT
(Delaware False Claims & Reporting Act, 6 Del. Code § 1201 *et seq.*)

267. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

268. Based on the foregoing allegations, Relator is liable under the Delaware False Claims & Reporting Act, 6 Del. Code § 1201 *et seq.*

COUNT NINE
(District of Columbia False Claims Act, D.C. Code § 2-381.01 *et seq.*)

269. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

270. Based on the foregoing allegations, Relator is liable under D.C. Code § 2-308.01 *et seq.*

COUNT TEN
(Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*)

271. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

272. Based on the foregoing allegations, Defendants are liable under Fla. Stat. § 68.081 *et seq.*

COUNT ELEVEN
(Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*)

273. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

274. Based on the foregoing allegations, Defendants are liable under the Georgia State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 *et seq.*

COUNT TWELVE
(Hawaii False Claims Law, HRS § 661-21 *et seq.*)

275. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

276. Based on the foregoing allegations, Defendants are liable under the Hawaii False Claims Law, HRS § 661-21 *et seq.*

COUNT THIRTEEN
(Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq.*)

277. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

278. Based on the foregoing allegations, Defendants are liable under the Illinois Whistleblower Reward & Protection Act, 740 ILCS 175/1 *et seq.*

COUNT FOURTEEN
(Illinois Insurance Claims Fraud Prevention Act, 740 Ill. Comp. Stat. 92/5(b))

279. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

280. 740 Ill. Comp. Stat. 92/5(b) provides that “[a]person who violates any provision of this Act, Section 17-8.5 or Section 17-10.5 of the Criminal Code of 1961 or the Criminal Code of 2012, or Article 46 of the Criminal Code of 1961 shall be subject, in addition to any other penalties that may be prescribed by law, to a civil penalty of not less than \$5,000 nor more than \$10,000, plus an assessment of not more than 3 times the amount of each claim for compensation under a contract of insurance.”

281. 740 Ill. Comp. Stat. 92/5(a) provides that “it is unlawful to knowingly offer or pay any remuneration directly or indirectly, in cash or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer.”

282. In violation of 740 Ill. Comp. Stat. 92/5(a), Defendants knowingly utilized runners, cappers, steerers, or other persons with respect to contracts of insurance.

283. Defendants violated 740 Ill. Comp. Stat. 92/5(a) with the intent to defraud insurance companies in Illinois.

COUNT FIFTEEN
**(Indiana False Claims & Whistleblower Protection Law,
Ind. Code § 5-11-5.5-1 *et seq.* (2005))**

284. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

285. Based on the foregoing allegations, Defendants are liable under the Indiana False Claims & Whistleblower Protection Law, Ind. Code § 5-11-5.5-1 *et seq.*

COUNT SIXTEEN
(Iowa False Claims Act, Iowa Code § 685.1 *et seq.*)

286. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

287. Based on the foregoing allegations, Defendants are liable under Iowa Code § 685.1 *et seq.*

COUNT SEVENTEEN
(Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:438.1 *et seq.*)

288. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

289. Based on the foregoing allegations, Defendants are liable under La. R.S. 46:438.1 *et seq.*

COUNT EIGHTEEN
(Maryland False Health Claims Act, Md. Code Ann. Health-Gen. § 2-601 *et seq.*)

290. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

291. Based on the foregoing allegations, Defendants are liable under the Maryland False Health Claims Act, Md. Code Ann. Health-Gen. § 2-601 *et seq.*

COUNT NINETEEN
(Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12 § 5A *et seq.*)

292. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

293. Based on the foregoing allegations, Defendants are liable under Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, § 5A *et seq.*

COUNT TWENTY
(Michigan Medicaid False Claims Act, Mich. Comp. Laws Ann. § 400.601, *et seq.*)

294. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

295. Based on the foregoing allegations, Defendants are liable under the Michigan Medicaid False Claims Act, Mich. Comp. Laws Ann. § 400.601 *et seq.*

COUNT TWENTY-ONE
(Minnesota False Claims Act, Minn. Stat. § 15C.01 *et seq.*)

296. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

297. Based on the foregoing allegations, Defendants are liable under Minn. Stat. § 15C.01 *et seq.*

COUNT TWENTY-TWO
(Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*)

298. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

299. Based on the foregoing allegations, Defendants are liable under Mont. Code Ann. § 17-8-401 *et seq.*

COUNT TWENTY-THREE
**(Nevada Submission of False Claims to State or Local Government Act,
Nev. Rev. Stat. Ann. § 357.010 *et seq.*)**

300. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

301. Based on the foregoing allegations, Defendants are liable under Nev. Rev. Stat. Ann. § 357.010 *et seq.*

COUNT TWENTY-FOUR
(New Jersey False Claims Act, N.J. Stat. Ann. § 2A:32C-1 *et seq.*)

302. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

303. Based on the foregoing allegations, Defendants are liable under N.J. Stat. Ann. § 2A:32C-1 *et seq.*

COUNT TWENTY-FIVE
(New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*)

304. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

305. Based on the foregoing allegations, Defendants are liable under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*

COUNT TWENTY-SIX
(New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1 *et seq.*)

306. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

307. Based on the foregoing allegations, Defendants are liable under the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-1 *et seq.*

COUNT TWENTY-SEVEN
(New York False Claims Act, N.Y. State Fin. Law, Art. 13, § 187 *et seq.*)

308. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

309. Based on the foregoing allegations, Defendants are liable under NY State Fin. Law, Art. 13, § 187 *et seq.*

COUNT TWENTY-EIGHT
(North Carolina False Claims Act, N.C. Gen. Stat. Ann. § 1-605 *et seq.*)

310. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

311. Based on the foregoing allegations, Defendants are liable under N.C. Gen. Stat. Ann. § 1-605 *et seq.*

COUNT TWENTY-NINE
(Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. tit. 63, § 5053.1 *et seq.*)

312. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

313. Based on the foregoing allegations, Defendants are liable under Okla. Stat. Ann. tit. 63, § 5053.1 *et seq.*

COUNT THIRTY
(Rhode Island False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*)

314. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

315. Based on the foregoing allegations, Defendants are liable under R.I. Gen. Laws § 9-1.1-1 *et seq.*

COUNT THIRTY-ONE
(Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*)

316. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

317. Based on the foregoing allegations, Defendants are liable under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

COUNT THIRTY-TWO
(Texas False Claims Act, Texas Human Resources Code, § 36.001 *et seq.*)

318. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

319. Based on the foregoing allegations, Defendants are liable under the Texas False Claims Act, Tex. Hum. Res. Code Ann. § 36.001 *et seq.*

COUNT THIRTY-THREE
(Vermont False Claims Act, Vt. Stat. Ann. tit. 32 § 630 *et seq.*)

320. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

321. Based on the foregoing allegations, Defendants are liable under the Vermont False Claims Act, Vt. Stat. Ann. tit. 32, § 630 *et seq.*

COUNT THIRTY-FOUR
(Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 *et seq.*)

322. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

323. Based on the foregoing allegations, Defendants are liable under Va. Code Ann. § 8.01-216.1 *et seq.*

COUNT THIRTY-FIVE
(Washington State Medicaid Fraud False Claims Act,
Wash. Rev. Code Ann. §§ 74.66, *et seq.*)

324. Relator realleges and incorporates by reference the foregoing paragraphs as though fully set forth herein.

325. Based on the foregoing allegations, Defendants are liable under Wash. Rev. Code Ann. § 74.66, *et seq.*

VII. PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States and the Plaintiff States, prays for judgment pursuant to the FCA and State FCAs as follows:

(a) For judgment against Defendants and in favor of the United States and the Plaintiff States for treble damages, civil penalties, expenses, attorneys' fees, and costs in connection with this action;

(b) For judgment against Defendants and in favor of the United States and the Plaintiff States for civil penalties in statutorily-determined amounts for each false claim;

(c) For an award to Relator for the maximum qui tam relator's portion permitted under the FCA and the State FCAs; and

(d) For an award to Relator for their reasonable expenses, attorneys' fees, and costs incurred in connection with this action.

VIII. JURY REQUEST

Relator hereby requests trial by jury.

Dated: February 13, 2024

Respectfully submitted,



Daniel R. Miller

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